TECHNICAL MANUAL

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OPTIMA PT-VS-ST

From Serial N° 18180100 till ...

A company of
Fresenius Kabi

Fresenius Vial
Infusion Technology

Revision table

TM Optima PT-VS-ST_en : ref NT1741

Date	Revision	Chapter	Description
03/04/03	0	All index "a"	création
20/08/07	1	Index "b"	New EMC standard, spare parts up date

1 Presentation 7
1.1 General presentation 7
1.2 Operation diagram 8
1.3 Precautions for use 9
1.4 Operation safety 9
1.5 Technical characteristics 9
1.5.1 Electrical details 9
1.5.2 Electronic details 9
1.5.3 Mechanical details 9
1.5.4 Conformity and norms 10

2 Description and operation 11
2.1 Physical description 11
2.1.1 Display board and front panel 12
2.1.2 The CPU board 14
2.1.3 The power supply board and battery 17
2.2 Operational description 19
2.2.1 Tube check and maintenance sub-assembly 19
2.2.2 Pumping sub-assembly 19
2.2.3 External connection sub-assembly 19

3 Description of the menus 21
3.1 Parameter configuration menu 21
3.1.1 Access to the menu 23
3.1.2 SAU 1, preventive maintenance configuration 24
3.1.3 SAU2, tube selection configuration 24
3.1.4 SAU3, "Beep" 25
3.2 Calibration menu 27
3.3 After-Sales Service test menu 29

4 Preventive maintenance 31
4.1 Recommendations 31
4.2 Maintenance schedule 31
4.2.1 Preventive maintenance 31
4.2.2 Quality control 31
4.3 Checks 33
4.3.1 Accessing the tests 33
4.3.2 Visual check 33
4.3.3 Operating period and maintenance date 34
4.3.4 Indicator lights test 34
4.3.5 Keyboard check 35
4.3.6 Battery voltage check 35
4.3.7 Checking the last 10 alarms 35

4.3.8 Checking the total operating period 37
4.3.9 Checking the analogue sensor input 37
4.3.10 Checking the software version 38
4.3.11 Checking the motor clamp (only **Optima VS**) 38
4.3.12 Checking the calibration values 39
4.3.13 Checking the infusion motor 39
4.3.14 Checking the last 10 events before a locking alarm or error 40
4.3.15 Checking the pressure alarm limit 40
4.3.16 Flow rate check 41
4.3.17 Air detector check 41
4.3.18 Battery autonomy check 41
4.3.19 Continuity test 42
4.3.20 Contrast check 42
4.3.21 Timestamp check 42
4.3.22 Quality Control Certificate 43

4.4 Cleaning and disinfecting 45

4.5 Storage 46

5 Troubleshooting 47

5.1 Breakdown guide 47

5.2 Error messages 51

6 Intervention procedures 55

N°1, Procedure: CPU board 57
N°2, Procedure: Display board 61
N°3, Procedure: Pumping system 65
N°4, Procedure: LCD display 69
N°5, Procedure: Air detector board 73
N°6, Procedure: Pressure sensor 77
N°7, Procedure: OCS clamp motor (if OCS is present) 81
N°8, Procedure: Power supply board 85
N°9, Procedure: Battery 87
N°10, Procedure: Front cover, base and angle bracket 89

7 Calibration 93

7.1 Calibration procedure 93
7.1.1 Access to the calibrations 93
7.1.2 CAL.1 Door calibration 94
7.1.3 CAL.2 Calibration of the flow rate corrective coefficient 95
7.1.4 CAL.9 Calibrating the upstream and downstream pressure sensors 96

8 Spare parts catalogue 99
8.1 Upper cover 99
8.2 Base 101
8.3 Optima pump angle bracket 103

1 Presentation

1.1 General presentation

The **Optima** pump is a new pump based on the same pumping mechanism as the MVP pump. It is used for infusion of intravenous agents.

There are three types of the **Optima** pump:

PT: for standard PVC tubes with a drop detector.

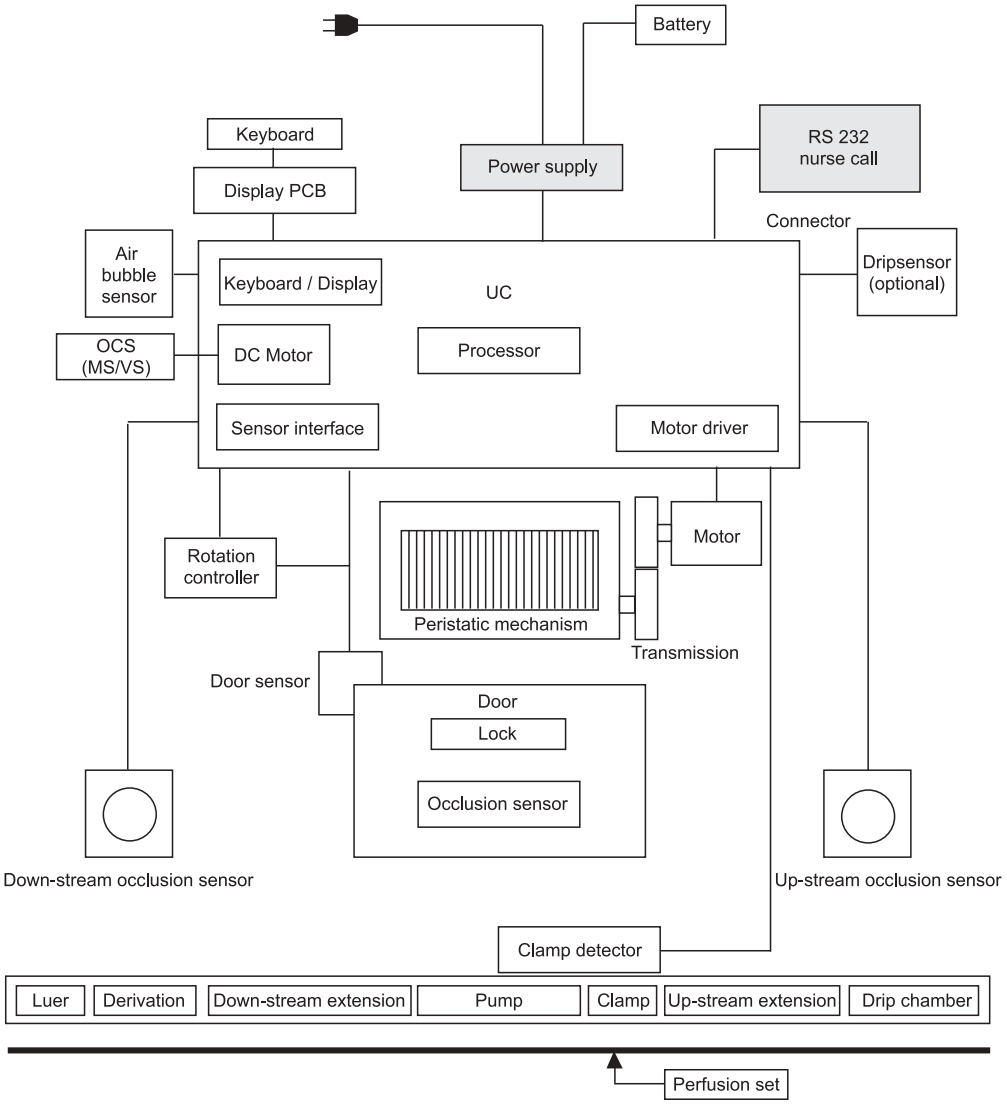
VS: for standard PVC tubes. The drop detector is optional. The pump is equipped with an automatic occlusion checking system (OCS).

ST: for silicon tubes equipped with a drop detector.

The **Optima** pump has its own control keyboard and distinct displays. It has an internal battery which ensures a minimum autonomy of 4 hours for a flow rate of 125 ml/h.

A choice of easily accessible configurations enables optimal use of the functions according to the needs of each department.

1.2 Operation diagram



Presentation

1.3 Precautions for use

The symbol ⚠ which appears on the device's condensed user instructions recommends a complete reading of the user instructions, in accordance with norm EN 60 601-1.

Fresenius Vial cannot, in any circumstances, be held responsible for any medical or other problem due to incorrect use of the device.

Kindly consult the user manual for more details.

1.4 Operation safety

As soon as it is in operation, the device ensures permanent surveillance of its functions. Any internal fault or any procedural anomaly is immediately detected. Nevertheless, abnormal functioning of the device, without a defined cause, must always be brought to the attention of the qualified staff in your establishment or our After-sales Service.

The **Optima** pump contains an internal battery which ensures normal functioning during a mains power cut. In addition, two fuses protect the affected mains area.

1.5 Technical characteristics

1.5.1 Electrical details

- External power supply: 100 - 240 Vac.
- Max. consumption: 50 VA.
- Battery: 6 V - 2.7/ 3 Ah - NIMH.
- Fuse: 2 x 630 mA T IEC 127.

1.5.2 Electronic details

The **Optima** volumetric pump has 4 electronic boards:

- CPU board
- Display board
- Power supply board
- Air detector board

1.5.3 Mechanical details

- Dimensions: H x L x W: 135 x 175 x 145 mm.
- Weight: approx. 2.9 kg

1.5.4 Conformity and norms

CE 0459	Conform to the 93/42/EEC Medical Directive.	**IP31** Protection against splashing liquid.
Safety of Electro Medical Equipements	Conform to EN/IEC 60601-1 and EN/IEC 60601-2-24.	Protection against leakage current: CF type.
EMC (ElectroMagnetic Compatibility)	Conform to EN/IEC 60601-1-2 (second index) and EN/IEC 60601-2-24.	Protection against electric shocks: class I.
⎓ Direct Courant	Equipotentiality	Fonctionnal earth.

Detailed information concerning electromagnetic compatibility is available in the chapter "Guidance and manufactureris declaration on EMC" of the User Manual.

2 Description and operation

2.1 Physical description

The **Optima** pump is made out of a front cover, a base and an angle bracket.

- The front cover contains:
  - a display board linked to the control panel,
  - a CPU board,
  - an air detector board,
  - the OCS system if OCS is present.

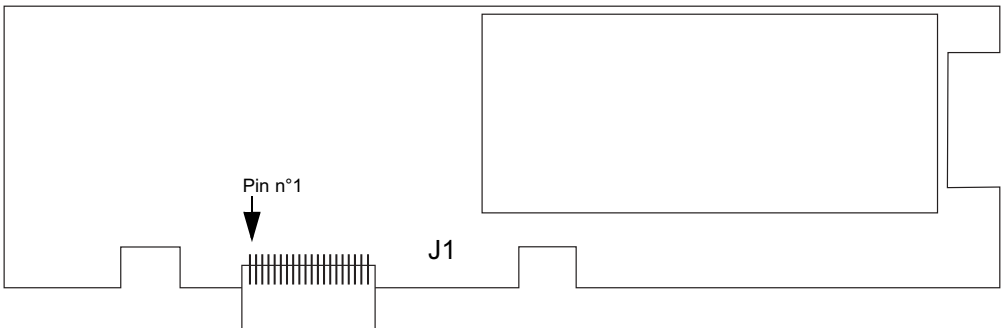
- The base supports the door and contains:
  - the pump body unit.

- The angle bracket contains:
  - a power supply board,
  - the battery.

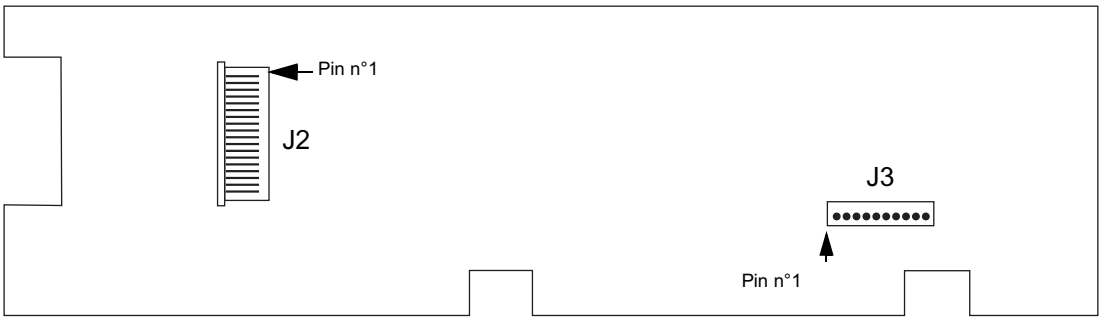
2.1.1 Display board and front panel

The display board is situated under the control panel and contains all the essential parts for the man-machine interaction:

- keyboard,
- synoptic and control indicators,
- 7-segment displays,
- LCD screen.



Display board LCD screen side.



Display board component side

This board is connected to the various equipment by means of connectors:

J1 connector to CPU board

Pin	Signal	Description
1	5V	Power supply
2	VBAT	Battery voltage
3	GND	
4	MOSI-AFF	Serial output
5	GND	
6	MISO-AFF	Serial input
7	GND	
8	CLK-AFF	Serial clock
9	GND	
10	CSLCD	LCD selection
11	GND	
12	CSAFCL	Display selected
13	GND	
14	A0AFF	LCD address
15	GND	
16	RESET/	
17	GND	

J1 connector to CPU board

Pin	Signal	Description
18	TON/OFF	ON/OFF Signal
19	VBAT	Battery voltage
20	5V	Power supply

J2 connector to LCD

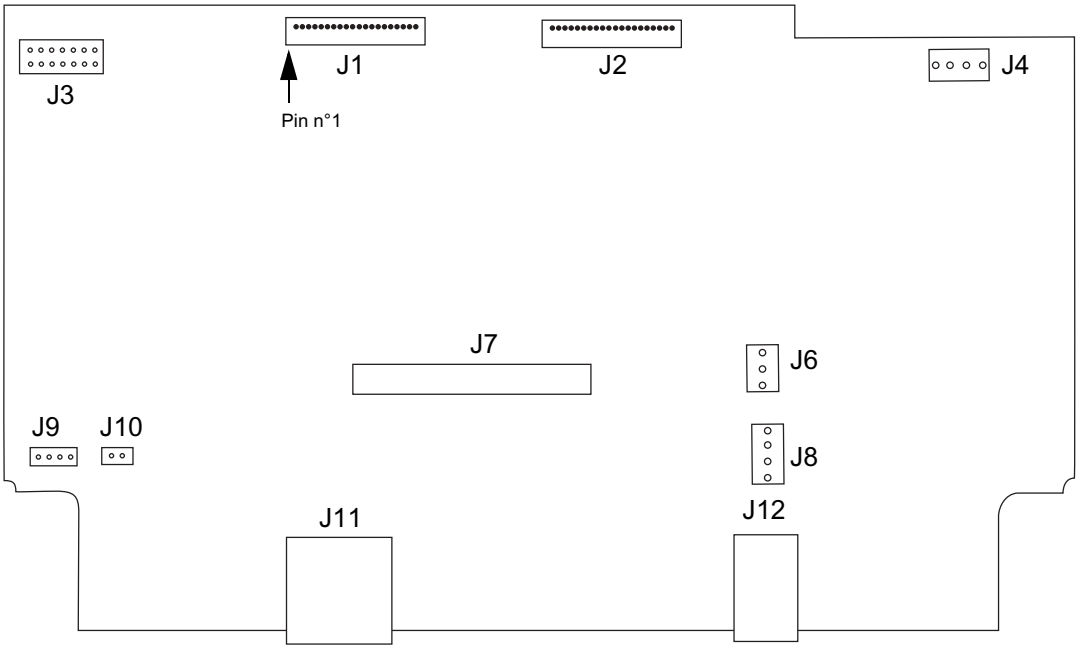
Pin	Signal	Description
1	+ led	VBAT + back light
2	- led	- back light
3	+5V	
4	/RESET	/RESET
5	VSS	Gnd
6	LD7	Data's writing
7	R/W	Gnd - Writing selection
8	LD6	Data's writing
9	A0AFF	LCD address
10	LD5	Data's writing
11	LD4	Data's writing
12	LD3	Data's writing
13	LD2	Data's writing
14	LD1	Data's writing
15	LD0	Data's writing
16	Enable	
17	LCDCS2	Chip select
18	/LCDCS1	Chip select

J3 connector to keyboard

Pin	Signal	Description
1	COL2	Keyboard interface column
2	COL1	Keyboard interface column
3	COL0	Keyboard interface column
4	Line 3	Keyboard interface
5	Line 2	Keyboard interface
6	Line1	Keyboard interface
7	Line 0	Keyboard interface
8	TON/OFF	On/Off
9	CONTRÔLE	
10	GND	

2.1.2 The CPU board

The CPU board contains a 80C32 micro-processor. It is connected to the display board by means of the J1 connector.



CPU board

Info: Pin 1 of connector J1 is opposite to that indicated by the CPU board screen printing.

J1 display board connector

Pin	Signal	Description
1	5V	Power supply
2	VBAT	Battery voltage
3	GND	
4	MOSI-AFFI	Serial output
5	GND	
6	MISO-AFF	Serial input
7	GND	
8	CLK-AFF	Serial clock
9	GND	
10	CSLCD	LCD selection
11	GND	
12	CSAFCL	Display selected
13	GND	
14	A0AFF	Address LCD
15	GND	
16	RESET/	
17	GND	
18	GNDTON/OFF	Signal ON/OFF
19	VBAT	Battery voltage
20	5V	Power supply

J12 drip detector connector

Pin	Signal	Description
1	Pulse-drip	Low signal yield
2	GND	
3	GND	
4	CDLED-drip	Control LED 5V/ 40 mA

J4 motor connector

Pin	Description
1	+Reel A
2	- Reel A
3	+Reel B
4	- Reel B

J6 power supply connector

Pin	Signal	Description
1	ALIM SECT	Power supply
2	GND	
3	ALIM EXT	Not used

J8 battery connector

Pin	Signal	Description
1	VBATNC	+ Battery
2	ANA-CTN	Temperature sensor Output
3	GND	
4	VBATNP	+ Battery before thermal fuse

J11 RS232 connector / Nurse call

Pin	Signal	Description
1	TxD-PC	Data reception from PC
2	RTS-PC	Request to send from PC
3	DTR-PC	PC terminal ready
4	RXD-PC	Transmission of data to PC
5	GND	
6	Nurse Call	Normally open contact
7	Nurse Call	Common contact
8	Nurse Call	Normally closed contact

J10 D.C. motor connector

Pin	Description
1	+ DC motor
2	- DC motor

J2 sensors connector

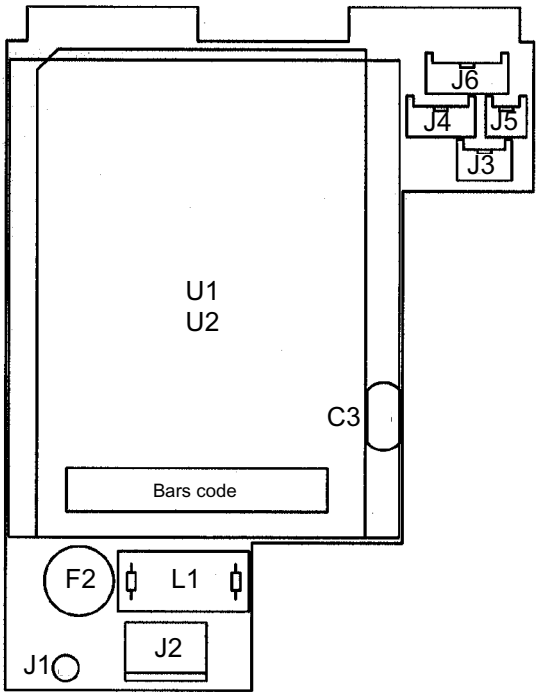
Pin	Signal	Description
1	GND	
2	/PRES_CLAMP	CLAMP presence
3	CD_CLAMP/	CLAMP detector power supply
4	+AMPLI_AM	Input + ampli sensor upstream pressure
5	- ALIM_AM	Upstream pressure sensor power supply return
6	- AMPLI_AM	Input - ampli upstream pressure sensor
7	+ ALIM_AM	Upstream pressure sensor power supply
8	GND	
9	-	Hall effect sensor power supply
10	GND	
11	ANA_HALL	Hall effect sensor output
12	+ AMPLI_AV	Input + ampli downstream pressure sensor
13	- ALIM_AV	Downstream pressure sensor power supply return
14	- AMPLI_AV	Input - ampli downstream pressure sensor
15	+ ALIM_AV	Downstream pressure sensor power supply
16	GND	
17	ET OPTO	State of sensor
18	GND	
19	+5 V	5 V power supply
20	-	Power supply sensor return

J9 air detector connector

Pin	Description	Description
1	/TST	Sensor test
2	5V	
3	GND	
4	/DETECT	Air bubble detection

2.1.3 The power supply board and battery

The power supply board is positioned on the angle bracket. It supplies power to the electronic unit from the 230 VAC network. It also ensures a battery charge of 2.7/3 Ah.



Power supply board

This board is connected to the various parts by means of connectors. F2 is time-delayed fuses of 630 mAT.

J1 functional Earth connector

J2 Mains connector

Pin	Description	
1	PH	Phase (100 - 240 Vac)
2	N	Neutral (100 - 240 Vac)

J3 power supply output connector

Pin	Description	
1	9V Sect	9V output convertor AC/DC
2	GND	
3	9V Ext	9V external power supply not used

J4 battery output connector to the CPU board

Pin	Description
1	+Vbat
2	+Thermal sensor
3	GND
4	VBAT NP

J6 battery input connector

Pin	Description
1	+ VBAT
2	VBAT NP
3	+ Thermal sensor
4	- Thermal sensor
5	GND

2.2 Operational description

From an operational point of view, the **Optima** pump is made up of 3 sub-assemblies:

- a sub-assembly to maintain to check the correct positioning of the tube,
- a motorisation sub-assembly,
- an external connection sub-assembly.

2.2.1 Tube check and maintenance sub-assembly

The tube is positioned along the front part and held in place by the door.

The front part is equipped with four detection systems:

- a detector to check the closed /open position of the door,
- an ultra-sound detector to detect the presence of air bubbles in the tube.
- The pressure detection is ensured by two piezo-resistant sensors.

2.2.2 Pumping sub-assembly

The pumping sub-assembly contains the peristaltic pumping mechanism.

The mechanism is made up of a camshaft that creates a wave-like movement in a bank of 14 'fingers'. The displacement of these 'fingers' is controlled by the CPU board, while turning it displaces the liquid at the programmed flow rate.

The cam shaft is driven by a stepper-motor and a reduction gearbox assembly via a toothed belt.
An optical disc attached to the end of the cam shaft controls its rotation.

2.2.3 External connection sub-assembly

The **Optima** contains two connectors located at the rear of the lower case:

- an RS 232 connector/Nurse call,
- a connector dedicated to the drip detector.

3 Description of the menus

3.1 Parameter configuration menu

The configuration menu adapts the **Optima** to the particular needs of each department. It accesses the menus that customise the infusion parameters.

Fresenius Vial recommends the presence of its qualified staff, or a member of your Technical Department, who will assist you in implementing the configuration procedures you wish to select.

The configuration mode is activated by holding down the "MODE" key when the device is switched on.

The following menus are displayed:

- User setting,
- Wards setting,
- Maintenance.

Each menu consists of sub-menus. The sub-menus can be accessed by using the "START" key.

To access some of the sub-menus, you need to type in an access code. This code can be defined and/or de-activated in the Service configuration mode. As long as the device is kept switched on, the code does not need to be keyed in again.

Main Menu	Key in code	Sub-menu	Sub-menu
User setting	Code XXXX		
		User setting menu	
Wards setting	Code 0200		
		Wards setting menu	
Maintenance	This code will be communicated at the end of the maintenance technician training.		
		Test	
			Maintenance tests menu
		After-sales configuration	
			Maintenance configuration menu
		Calibration	
			Calibration menu

Maintenance	Test	tESt.1	operating period and maintenance date
		tESt.2	LED, LCD screen, 7-segment display and buzzer test
		tESt.3	keyboard test
		tESt.4	display's the battery voltage
		tESt.5	display's the last 10 alarms codes
		tESt.6	display's the total running time
		tESt.9	display's the analogue sensor values
		tESt.A	display's the software version
		tESt.C	clamping motor test
		tESt.E	display's the calibration values
		tESt.F	infusion motor test
		tESt.J	display's the code last 10 alarm codes before error
	Configuration	SAU.1	preventive maintenance
		SAU.2	tube selection
		SAU.3	Beep
	Calibration	Etal.1	door calibration
		Etal.2	corrective infusion coefficient
		Etal.9	upstream and downstream pressure sensors calibration

The maintenance menu is reserved for qualified staff only.

3.1.1 Access to the menu

Key	Function
	ON switches on the device. **OFF** switches off the device and exits the configuration mode when pressed for more than three seconds.
	SILENCE ALARM
	MODE accesses the configuration mode.
	The selection keys scroll through the numbers and letters, the tenths, units and tens values. Activate or de-activate choices.
	ENTER moves the cursor.
	START validates a selection.
	STOP cancels the current configuration.

Activate the After-Sales Service test menu.

- Keep the "MODE" button pressed, during the device switch on.
  - ☐ The various menus are displayed.

- Select the "Maintenance" menu and confirm.
- Type in the access code and confirm.
- Select "Sav" and confirm.

- Use the selection keys to scroll through the various tests on the LCD display.

3.1.2 SAV 1, preventive maintenance configuration

■ SAV 1, press "START".

- ☐ The running time since the last maintenance in hours and the date are displayed on the LCD screen.
- ☐ To move the cursor use the enter key.

- ☐ Use the selection keys to modify a field.

- ☐ By validating once again, the new running time and date are memorised and you may return to the After-sales Service menu.

By pressing "STOP" you can cancel the modification and return to the After-sales Service configuration menu.

You can exit the configuration mode at any time by pressing the "OFF" key.

3.1.3 SAV2, tube selection configuration

■ SAV2, press "START".

- ☐ The list of available tubes is displayed on the LCD screen.

The tubes which have already been calibrated for pressure are marked with a "v".

- ☐ Select the tube using the keys.

- ☐ Press "START" to save the tube selection.

- ☐ When the device is switched on, the selected tube will appear on the display unit.

By pressing "STOP", the modification is cancelled and you can return to the After-sales Service configuration menu.

You can exit the configuration mode at any time by pressing the "OFF" key.

3.1.4 SAU3, "Beep"

This option is available on Optima pump equipped with software version 1.8e minimum.

- SAU3, press "START".

- ○ + 10 s. (not activated)
- ■ + 0 s. (activated)
  - □ Select your choice using the key.
    - 10 s: the audible alarm "Beep" is triggered every 10 seconds.
    - 0 s: the audible alarm "Beep" is triggered every 0 second.

  - □ Press "START" to record your selection.

By pressing "STOP", the modification is cancelled and you can return to the After-sales Service configuration menu.

You can exit the configuration mode at any time by pressing the "OFF" key.

3.2 Calibration menu

The calibration menu is reserved for qualified staff only. Its access is protected by a secret code. To find out about the operating mode for the various calibrations, refer to the "Calibrations" chapter.

This menu enables manual calibration of:

- CALI.1: the door,
- CALI.2: the corrective coefficient for the infusion flow rate by tube type,
- CALI.9: the upstream and downstream pressure sensors.

3.3 After-Sales Service test menu

The After-Sales Service test menu is reserved for qualified personnel. It enables a series of checks that can be carried out on the **Optima** pump to confirm it is operating correctly. (See chapter **"Checks**"). These must be carried out each time parts are replaced.

The After-Sales Service tests can also be carried out more quickly and simply from a PC using our maintenance software. (Contact our After-Sales Service department.)

The Service test menu contains a series of 17 tests or checks:

- tESt.1: operation period and maintenance date display
- tESt.2: indicator lights test
- tESt.3: keyboard test
- tESt.4: battery voltage test
- tESt.5: display's the last 10 alarms codes
- tESt.6: display's the total operating period
- tESt.9: display's the analogue sensor values
- tESt.A: display's the software version
- tESt.C: clamping motor test (only **Optima VS**)
- tESt.E: display's the calibration values
- tESt.F: infusion motor test
- tESt.J: display's the last 10 alarm codes before error

A log of more than 760 time-stamped events can be consulted using our maintenance software "VP Control". (Contact our After-Sales Service department.)

4 Preventive maintenance

4.1 Recommendations

The **Optima** pump can only be checked, serviced or repaired by **Fresenius Vial** or by a certified and approved maintenance service. Any abnormal functioning of the pump must be brought to the attention of your in-house qualified technical personnel or our After-Sales Service.

Should you need to return the pump to our After-Sales Service, it should be cleaned, disinfected and very carefully packaged, preferably in its original packaging, before being sent.

For all information concerning the repair and use of the pump, kindly contact our After-Sales Service or our Sales department.

Fresenius Vial is not liable for loss or damage to the pump during its transport to our After-Sales Service.

4.2 Maintenance schedule

4.2.1 Preventive maintenance

In order to maintain the pump's performance, a Preventive Maintenance inspection must be carried out every 3 years. This procedure, which includes changing the battery, should be carried out by a qualified technician.

Any abnormal functioning or failure must be reported to the qualified technical staff in your organisation or to our After-Sales Service. In these instances, the pump should not be used.

Important: If these maintenance procedures are not observed, the pump's correct operation will be impaired.

4.2.2 Quality control

At the request of the health organisation, a quality check will be carried out every 12 months.

A quality check (not included in the guarantee) consists of different inspection procedures as defined in the pump's Technical Manual. Only a qualified technician may perform the quality check which must be performed using Fresenius-Vial software.

For more information, kindly contact our After-Sales Service.

At the end of the device life, return it to an organization competent in the treatment of the electrical an electronic equipment waste. Remove the battery from the device and return it to competent recycling organization.

4.3 Checks

In order to ensure the preventive maintenance follow-up, a regular servicing inspection is recommended every 12 months (see "Quality Control Certificate").

Recharge the battery during 16h before starting the checking procedure !

4.3.1 Accessing the tests

Keyboard description.

Key	Function
	ON switches on the device. **OFF** switches off the device when pressed for over three seconds.
	SILENCE ALARM
	STOP, cancels the current test.
	START validates a selection.
	MODE accesses the test mode.
	The selection keys scroll through the numbers and letters on the tenths, units and tens values, and activate or de-activate the infusion menus.
	ENTER validates your test selection or moves the cursor.

Activate the After-Sales Service test menu.

- Keep the "MODE" button pressed, during the device switch on.
  - The various menus are displayed.

- Select the "Maintenance" menu and confirm.
- Type in the access code and confirm.
- Select "Test" and confirm.

- Use the selection keys to scroll through the various tests on the LCD display.

4.3.2 Visual check

Check the general aspect of the case and labels and check for shock impact damage.

4.3.3 Operating period and maintenance date

This test displays the **Optima's** running time since its last servicing inspection. It also displays and modifies the "last" servicing inspection date. When the servicing inspection date is modified, the operating time is resetted.

■ tESt.1, press "START".

- ☐ The operating time and the last service inspection date are displayed on the LCD screen.
- ☐ If "Preventive test" flashes, service inspection is required.
- ☐ Press on the "Enter" key to select the date.

When reading this information, it is possible to modify the day, month and year of the service inspection date using the units and tens keys. This date will be stored in EEPROM and the operating time is reseted to zero.

- ☐ When validating again, a new test can be selected.

You can interrupt the test at any time by pressing "STOP" and returning to the test selection.

4.3.4 Indicator lights test

This test checks the correct functioning of the indicator lights, the LCD screen display, front panel and buzzer.

■ tEPSt.2, press "START".

- ☐ All the leds, 7-segment displays and the LCD lighten up.
- ☐ When validating again
  - ♦ the leds and displays scroll across one by one from left to right (leds display, 7 segment display by segment and then by section of 8).
  - ♦ An image scrolls across the LCD screen.

The test is OK if all the indicator lights have lit up and the buzzer has gone off.

You may interrupt the test at any time by pressing "STOP" and returning to the test selection.

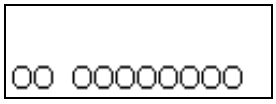
If the display is faulty, replace the display board (see "Display Board procedure).

4.3.5 Keyboard check

This test checks that the keyboard keys are functioning correctly.

■ tESt.3, press "START".

☐ The following screen appears:
☐ Press each key one by one,
  ♦ The keys that have been pressed appear as a reverse video image on the LCD screen.



If two keys or more are held down simultaneously, "beep! beep! beep!" will be heard, indicating an error.

You may exit the test at any time by pressing **"START" for more than 3 seconds**, returning to the test selection.

4.3.6 Battery voltage check

This test displays the mains or battery voltage in volts or in tenths of volts.

■ tESt.4, press "START".

☐ The voltage is displayed in volts.

  ♦ If the **Optima** pump is running on battery, the LCD screen displays, for example:

  ♦ If the **Optima** pump is running on the mains, the LCD displays, for example:

☐ By confirming once again, a new test may be selected.

4.3.7 Checking the last 10 alarms

This test displays in code form the last ten alarms which have been triggered on the **Optima** pump.

■ tESt.5, press "START".

☐ The code for the most recent alarm is displayed at the top of the LCD screen.

☐ Press the selection keys to display the following codes from 1 to 10.

☐ By validating once again, a new test may be selected.

Alarm or error codes description:

Alarm	Description
A10	Battery alarm
A12	End of infusion alarm
A16	Downstream occlusion alarm
A17	Air detection alarm
A18	Air volume alarm
A19	Upstream occlusion alarm
A20	Tube absence alarm
A21	Mobile clamp absence alarm.
A22	Door alarm
A23	Drip detector absence alarm
A24	Drip detector alarm: under flow
A25	Drip detector alarm: over flow
A26	Free flow
A27	Occlusion problem during auto-set
OFF	Normal stop
FAIL	Abnormal stop

Error	Description
Er10	Internal RAM
Er20	External RAM
Er30	Check-sum Flash
Er40	Access (E^2prom) Eeprom
Er50	Access Adc
Er60	Tube parameters
Er70	Motor frequency
Er80	Keyboard matrix (key press non functioning)
Er90	Check-sum Flash or software version µC secondary
Er01	Rotation (absence top turn)
Er11	Rotation (white or black too great)
Er21	Rotation (incorrect number of turns)
Er31	Automatic clamping motor
Er41	Rotation (presence top turn)
Er14	Period calculation parameters verification
Er24	Rotation direction verification
Er44	Incoherence quartz µC principal and µC secondary
Er54	Absence display board
Er74	Battery disconnection (3)
Er84	Battery charge (3) fault
Er94	Battery temperature fault
Er55	µC secondary access
Er65	Absence LCD display back light

Error	Description
Er85	Restart µC secondary
Er16	Date and time in µC secondary verification
Er56	Association condition output/step number
Er17	Keyboard matrix (key press and columns inactive)
Er27	Keyboard check default (path not fine tuned)
Er37	ON/OFF key locked
Er47	Switching off impossible
Er28	Language file incompatible

4.3.8 Checking the total operating period

This test displays the total period of operation for the **Optima** pump. The value cannot be modified manually.

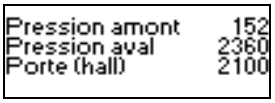
■ tESt.6, press "START".

- ☐ The running time is displayed on the LCD screen.
- ☐ By confirming once again, a new test may be selected.

4.3.9 Checking the analogue sensor input

■ tESt.9, press "START".

- ☐ The LCD screen displays:
  - Upstream pressure, e.g.:
  - Downstream pressure, e.g.:
  - Door sensor, e.g.:



- ☐ By confirming once again, a new test may be selected.

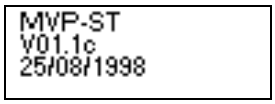
If the value is out of limits, recalibrate the force sensor. (See "ttAL9 upstream and downstream pressure sensors calibration").

4.3.10 Checking the software version

This test displays the software version and revision numbers.

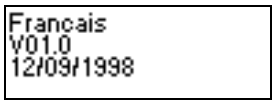
■ tESt.A, press "START".

- ☐ The LCD screen displays:
  - the name of the **Optima** pump.
  - the software version.
  - the date.



- ☐ Press the tenths keys to continue the test.

- ☐ The LCD screen displays:
  - the language versions.

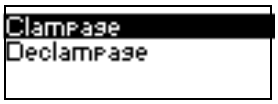


- ☐ By confirming once again, a new test may be selected.

4.3.11 Checking the motor clamp (only Optima VS)

■ tESt.C, press "START".

- ☐ The LCD screen displays:
  - clamping
  - unclamping



- ☐ Moving from clamping to unclamping occurs automatically after confirming one of the two functions using the selection keys.

- ☐ Press "START" to carry out the clamping or unclamping.

You may interrupt the test at any moment by pressing "STOP" and returning to the test selection.

4.3.12 Checking the calibration values

This test displays the calibration values recorded in the EEPROM.

■ tESTE, press "START".

□ Move to another value using the keys.

Display	Description
Por 1	Hall effect sensor, door closed without tube.
Por2	Hall effect sensor, door open.
Por3	Hall effect sensor, door closed with filled tube.
PAN 1	Upstream pressure, door open.
PAN2	Upstream pressure, 0 mmHg, with filled tube.
PAU 1	Downstream pressure, door open.
PAU2	Downstream pressure, 0 mmHG, with filled tube.
PAU3	Downstream pressure, 750 mmHg, with filled tube.

■ By confirming once again, a new test may be selected.

The value between brackets after the title is the number of calibrations carried out. The display of the upstream and downstream pressure values is carried out according to the number of active tubes.

4.3.13 Checking the infusion motor

This test starts the motor without activating any infusion alarms.

■ tEST.F, press "START".

□ Select an infusion flow rate (0.1 ml/h to 1000 ml/h) using the keys.

□ Press "START" to confirm the flow rate and start up the motor.

If a motor rotation problem is detected, the LCD screen disappears and Er01, Er11 or Er21 appears on the 7-segment display. By pressing "STOP" you may exit the error and return to the test.

The test may be interrupted at any time by pressing the "STOP" key and a new test may be selected.

4.3.14 Checking the last 10 events before a locking alarm or error

This test enables the visualisation of the codes for the last 10 events that have occurred during operation of the device before the last locking error.

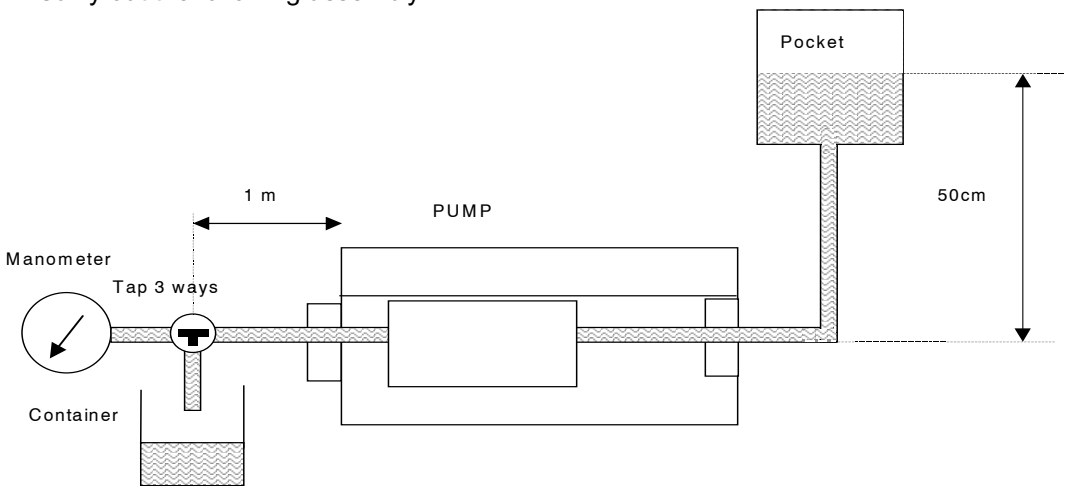
■ tESt.J, press "START".

- ☐ The number of times the machine has been switched on since the last locking error is displayed on the LCD screen.
  - "A" for an alarm. (See table tESt.5)
  - "E" for an error. (See table tESt.5)
- ☐ By validating once again, a new test may be seleted.

4.3.15 Checking the pressure alarm limit

To carry out this operation, exit the test mode and press "OFF".

■ Carry out the following assembly



■ Press "ON".

- ☐ Position a tube in the device and lock the door inserting the clamp.
- ☐ Position the manometer at the outlet of the tube.
- ☐ Select a flow rate of 125 ml/h.
- ☐ Adjust the pressure threshold to 750 mmHg.
  - Let the tap run in a container.
  - Start up the infusion and leave it running for 30 seconds.
  - Position the tap to the manometer.
  - Check that the alarm is triggered for a value of 1 bar ± 0.15 bar.
- ☐ Stop the infusion by pressing "STOP".

If the measured pressure value, depending to the limit selected is out of range, recalibrate the pressure sensors. (See"CAL 9 Calibration of the upstream and downstream pressure sensors".)

4.3.16 Flow rate check

- Connect the **Optima** pump to the mains.

Before any flow rate test, run out an infusion of 20 ml to stabilise the flow rate.

To carry out this test, we recommend to use the IS Flow rate software available with Fresenius Vial.

- Carry out a flow rate test according to the norm EN 60601-2-24.
- Check that the flow rate error lies between - 5% et + 5%.

If the discrepancy is too significant, refer to chapter 7 "Calibration / Calibration procedure / ETAL2 Calibrating the flow rate corrector coefficient".

4.3.17 Air detector check

To carry out this test, exit the test mode.

- Position a tube filled with water in the device.
- Press "ON".
  - ☐ Select a flow rate of 100 ml/h.
  - ☐ Press "START" to start up the infusion.
  - ☐ Turn the drop chamber upside down to create an air bubble of around 5 cm.
  - ☐ Check that the alarm is triggered when the air bubble crosses the detector.

The audio alarm can be stopped by pressing "SILENCE ALARM". (Default running time is 2 minutes.).

4.3.18 Battery autonomy check

- Recharge the battery for at least 16 hours (100% capacity).
- Press "ON".

  - ☐ Position a filled tube at a flow rate of 125 ml/h, then confirm.
  - ☐ Check the battery autonomy is at least 4 hours.

4.3.19 Continuity test

Use a multimeter.

To carry out this procedure, exit the test mode. Press "OFF.

■ Using a calibrated multimeter in ohms, check the presence of an electrical resistance greater than 10 MΩ between:

- ☐ between the phase and equipotential pin.
- ☐ between the neutral and equipotential pin.

4.3.20 Contrast check

To carry out this procedure, go to the "User configuration" menu.

- ☐ Key in the access code (if asked).
- ☐ Select "LCD contrast" and confirm.
- ☐ Check that the central portion of the screen is slightly darker and adjust the contrast if necessary using the selection keys.

- ☐ By pressing the confirm key, you can exit the test.

4.3.21 Timestamp check

To carry out this procedure, go to the "User configuration" menu.

- ☐ Key in the access code (if asked).
- ☐ Select "Time setting" and confirm.
- ☐ Check if the date and time are correct.

If necessary, adjust the date and time using the selection keys and the ENTER key to move from one figure to another.

- ☐ By pressing the confirm key you can exit the test.

4.3.22 Quality Control Certificate

Use this table to summarise the results obtained from the various tests.

These tests can be done with a software dedicated to **Optima**.

Device type:	**Code:**	**Device serial n°:**

N°	Procedure	Obtained value	Conformity Yes	Conformity No
1	■ Check the general appearance of the case, labels, serial number and product code.			
2	■ Check the contrast. If a fault is observed, refer to chapter 'Contrast Check'.			
3	■ Check the clock. If an adjustment is needed, refer to chapter on datestamp checking.			
4	■ Display the operating period, tESt.1 and the maintenance date.			
5	■ Check the indicator lights, tESt.2.			
6	■ Check the keyboard, tESt.3.			
7	■ Display the total running time, tESt.6.			
8	■ Occlusion check, tESt.F ☐ Connect the water manometer to the tube outlet. ☐ Start up test F. ☐ Check that there is no motor error and that the maximum pressure is above 2 bar (1500 mmHg) for the version PT and ST, above 1.6 bar for the version ST.			
9	■ Check clamping and unclamping, tESt.C. (if OCS is present) ☐ Confirm the two functions. ☐ Check for any absence of motor alarm.		.	
10	■ Check the drop detector (if the detector is present). ☐ Start up an infusion. ☐ Check the (green) drop indicator lights up each time a drop appears in the drop chamber. ☐ Disconnect the detector. ☐ Check if the drop alarm is activated.			
11	■ Check the air detector. ☐ Create an air bubble in the tube of at least 5 cm long. ☐ Check the presence of the air bubble alarm (sound and visual) while the air bubble is in the air bubble detector.			
12	■ Check the downstream pressure. ☐ Install a calibrated water manometer at the tube outlet. ☐ Adjust the pressure threshold to 750 mmHg. ☐ Start an infusion at 100 ml/h. ☐ Check that the downstream occlusion alarm is activated at 750 mmHh +/-125 (1 bar +/-0.15). If there is a too great discrepancy, refer to chapter 7 "Calibration / Calibration procedure / EtAL.9 calibrating the upstream and downstream pressure sensors".			

N°	Procedure	Obtained value	Conformity Yes	Conformity No
13	■ Check the upstream pressure. (Only **Optima VS**) ☐ Start an infusion at 100 ml/h without drop detector. ☐ Clamp the tube between the drop chamber and the pump. ☐ Check that the **upstream** occlusion alarm is activated within 10 seconds. ☐ Unclamp. ☐ Check that the confirmation indicator lights up.			
14	■ Check the clamp. ☐ Place a water pipe in the device. ☐ Close and open the door. ☐ Check that the clamp lock the tube. ♦ There should be no dripping at the tube outlet.			
15	■ Check the battery operation. ☐ Disconnect the mains lead. ☐ Check the presence of the battery indicator. ☐ Reconnect the mains lead. ☐ Check if the battery indicator is switched off and that the mains indicator lights up.			
16	■ Check the flow rate. *Before any flow rate test, run an infusion of 20 ml to stabilise the flow rate.* ☐ Carry out a flow rate check in accordance with the norm EN 60601-2-24. ☐ Check that the flow rate error is between - 5% and + 5%. If there is too much discrepancy, refer to chapter 7 "Calibration / Calibration procedure / ETAL.2 calibrating the flow rate corrector coefficient".			
17	■ Check the battery autonomy. ☐ Start an infusion at 125 ml/h for 4 hours.			
18	■ Carry out an electrical safety test according to norm EN 60601-1-2			

Name:	Date:	Visa:

Observations:

4.4 Cleaning and disinfecting

The pump form part of the patient's immediate environment. It is advisable to clean and disinfect the device's external surfaces of the device on a daily basis in order to protect patient and staff.

- Disconnect the Base from its mains supply before cleaning.
- Do not place in an AUTOCLAVE nor IMMERSE the device, Do not let liquids enter the device's casing.
- If the device is placed in a high contamination risk unit, it is advisable to leave it in the room during disinfecting, after having disinfected it with amoist cloth.
- Use a cloth soaked in DETERGENT-DISINFECTANT, previosly diluted with water if required, to destroy micro organisms.
  - Avoid abrasive scrubbing which could scratch the casing.
  - Do not rinse or wipe the surfaces.

Do not use :

- ¨TRICHLOROETHYLENE-DICHLOROETHYLENE
- AMMONIA.
- AMMONIUM CHLORIDE
- CHLORINE AND AROMATIC HYDROCARBON.
- ETHYLENE DICHLORIDE-METHYLENE
- CHLORIDE-CETONE

These aggressive agents could damage the plastic parts and cause device malfunction.

Take car also with ALCOHOL based SPRAYS (20% -40% alcohol) .They lead to tarnishing and small cracks in the plastic, and do not provide the neceeeary cleaning prior to disinfection.

Disinfecting SPRAYS may be used, in accordance wih the manufacturer recommendation, from a distance of 30 cm of the device, avoid the accumulation of the product in liquid form.

Avoid iodine-based solutions that may result in coloring some plastic parts permanently.

Please contact the appropriate service, responsible for cleaning and disinfecting products, in your establishment for further details.

4.5 Storage

The device should be stored in a dry, cool place. In case of prolonged storage, the battery should be disconnected via the battery access flap situated underneath the device.This should be done by a qualified technician

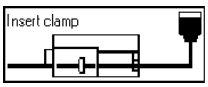
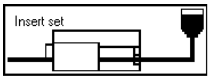
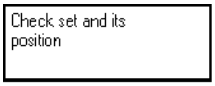
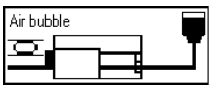
- Storage conditions and carrying:
  - Temperature: -10°C to 60°C / 14°F to 140°F.
  - Atmospheric pressure: 500 hPa to 1060 hPa.
  - Humidity: 10% to 90%, no condensation.

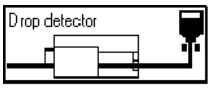
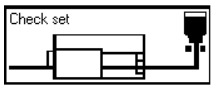
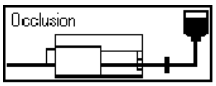
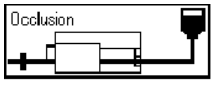
- Use conditions:
  - Temperature: 5°C to 40°C / 41°F to 104°F.
  - Atmospheric pressure: 700 hPa to 1060 hPa.
  - Humidity: 20% to 90%, no condensation.

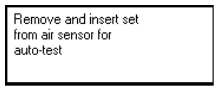
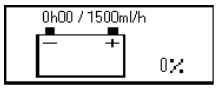
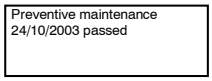
Fully recharge the battery before using the equipment to avoid any risks caused by micro power cuts in the mains supply and to ensure maximum autonomy.

5 Troubleshooting

5.1 Breakdown guide

Message on LCD display	Meaning	Causes	Action
	Door open alarm	■ Hall affect sensor detects that the door is open	■ Check set installation ■ Check the presence of the door magnet ■ Calibration of the door sensor ■ Replace the door sensor
	Clamp position alarm	■ The Optima does not detect the presence of the set securing clamp	■ Check set installation ■ Check the securing clamp micro switch ■ Replace it if necessary
	Set insertion alarm	■ Wrong position of the set	■ Check set installation ■ Check the presence of the door magnet ■ Calibration of the door sensor ■ Replace the door sensor
	OCS test Alarm	■ Occlusivity test not successful. The pumping mechanism does not succeed to increase the pressure in the IV set during the OCS test	■ Check set installation ■ Check the door and carry on a calibration if necessary ■ Verify the good condition of the membrane. Replace it if necessary; refer to the maintenance protocol : PM 0094
	Air bubble alarm	■ Air volume detected is higher Than the limit programmed ■ Set is not properly inserted in the air detector	■ Prime the line to remove the air ■ Check set installation on the air detector Verify the air adjustment of the air size programmed ■ Replace the air detector or air bubble board

Message on LCD display	Meaning	Causes	Action
	Drop alarm (If drop detector is present)	■ The container is empty ■ The rolling clamp is closed ■ Over-flow , under flow, free flow ■ The position of the drop sensor ■ Drop chamber is full ■ Drop detector is disconnected while the pump is configured to be used with ■ The drip sensor is connected and disconnected	■ Verify the volume remaining on the container ■ Verify if the roller clamp is open ■ Verify if the air inlet cap if open when the pump is used with a bottle ■ Verify the positioning of the drop detector ■ Verify the volume of the liquid in the drop chamber ■ Verify the IV set position ■ Verify the drip sensor is well connected ■ Verify the connector if it's damaged ■ Replace the drip sensor
	Free flow alarm (in case of use with drip sensor)	■ Over-flow ■ Set not properly positioned	■ Check set installation ■ Check drip sensor positioning
	Upstream occlusion alarm	■ Upstream pressure in line is too low ■ Empty container ■ Check the roller clamp ■ Air inlet cap is closed (bottle used)	■ Check container ■ Check roller clamp ■ Check if the set is not squeezed ■ Check the container height ■ Check the air inlet cap (if bottle used) ■ Check the calibration values (Test 9) ■ Proceed to the calibration of pressure ■ Replace the force sensor
	Downstream pressure alarm	■ The pressure in line exceeds the limit programmed	■ Check the infusion line ■ Check the correspondence between the limit programmed and detected ■ Check the pressure sensor (Test 9) ■ Proceed to the calibration of the force sensor ■ Replace the force sensor

Message on LCD display	Meaning	Causes	Action
	Air alarm	■ The IV set is present on the air bubble detector but not on the pumping mechanism ■ The pump runs over 24 hours, no air bubble have detected by the sensor	■ Remove the IV set and re-install it ■ Carry on a calibration of the door
	Battery alarm	■ Low battery voltage	■ Connect the pump to the mains power ■ Check the charging voltage, pump connected to the mains. ■ Replace the battery
	Preventive maintenance requested	■ Preventive maintenance date or time is passed	■ Proceed to the complete check up of the pump and update the maintenance date or time (test 1)

Problems	Causes	Action
Flow rate drift	■ The installed set doesn't correspond with the set selected ■ A mechanical part which has a link with the pumping mechanism or the CPU board has been changed without calibrating the flow rate correcting coefficient	■ Check the set selection ■ Measure the flow rate using a reference set and calibrate the flow rate correcting coefficient
Display defect: LED's, 8 segments display units	■ Control transistors, LED's and/or display board connection are defective	■ Check the LED's and display (test 2) ■ Check the good condition of the display board ■ Replace the LED's ■ Check the connector which link CPU and display boards ■ Replace the display board
The device turns off when it is disconnected from mains power	■ The battery is unplugged or the battery cable is cut ■ Battery is totally discharged	■ Check the battery connection ■ Check the charging voltage ■ Replace the battery
Mains LED's does not switch ON	■ Mains fuses out of order ■ Power supply out of order	■ Replace Check the mains fuses ■ Replace the power supply board ■ If the problem remains, replace the CPU board

Problems	Causes	Action
Battery alarm while it has been completely charged	■ Battery is totally discharged	■ Check the charging voltage ■ Replace the battery
Battery alarm whereas the Optima is connected to the mains	■ Power supply or CPU boards are faulty	■ Check the charging voltage ■ Check the power supply mains fuses ■ Replace the power supply if necessary. ■ If the problem remains, replace the CPU board and carry on a complete configuration
The module MVP turns ON or turns OFF alone	■ Keyboard is defective ■ CPU board is defective	■ Check the keyboard (test 3) ■ Replace the keyboard if necessary ■ Check that there was no liquid infiltration on the CPU board ■ Replace the CPU board and carry on a complete configuration of the device
Some keys from keyboard out of order	■ Keyboard is defective	■ Check the keyboard (test 3) ■ Replace the keyboard if necessary
After a fall	■ Mechanical elements damaged	■ Check that the mechanical assembly and the cases are intact
Pump noisy	■ Power supply and CPU wires are closed to the motor (earth wire also)	■ Fix the wires as it shown on the technical manual

5.2 Error messages

Error codes	Meaning	Action
Electronic and software command anomalies *		
Er 10	Internal RAM Anomaly	■ Carry on a complete configuration of the device via VP Control software ■ Replace the CPU board and carry on a complete configuration
Er20	External RAM Anomaly	
Er30	EPROM Anomaly	
Er40	EEPROM Anomaly	
Er50	ADC Anomaly	■ Check the ADC ■ Replace the CPU board and carry on a complete configuration
Er60	Sets parameters anomaly	■ Reconfigure the module MVP with VP Control software ■ Replace the CPU board and carry on a complete configuration
Er70	Motor frequency anomaly	
Er80	Keyboard anomaly	■ Check and replace the keyboard if necessary ■ Check that there is no liquid presence inside the device which could damage keyboard and the electronics boards ■ Replace the CPU board and carry on a complete configuration
Er90	Software version	■ Configuration of the device is needed through with VP Control ■ Replace the CPU board and carry on a complete configuration
Er01	Stepper motor rotation error	■ Replace the motor
Er11	Stepper motor rotation error	■ Check the motor coupling See PM 0094
Er21	Stepper motor rotation error	■ Replace the mechanical block See PM 0094
Er31	OCS DC motor failure	■ Check the motor clamp for OCS and rubber O ring ■ Put some grease on the clamp finger threaded screw. Replace the rubber O ring if necessary (p/n: 174256) ■ Replace the OCS motor clamp
Er41	Stepper motor rotation error	■ Replace the motor

Error codes	Meaning	Action
Er 14	Motor period calculation anomaly	■ Reconfigure the device with VP Control software ■ Replace the CPU board and carry on a complete configuration of the device
Er24	Motor rotation direction anomaly	■ Check the motor rotation sensor ■ Replace the CPU board and carry on a complete configuration of the device
Er44	Quartz frequency anomaly	■ Replace the quartz ■ Replace the CPU board and carry on a complete configuration of the device
Er54	Display board anomaly	■ Check the display board connection and replace it if necessary
Er74	Battery disconnected	■ Check the battery connection
Er84	Battery charging failure	■ Check the charging voltage ■ Ensure that the charging time is not over 15 hours ■ Replace the battery
Er94	Temperature fault	■ Replace the battery ■ Replace the CPU board
Er55	Access default to the secondary µ processor	■ Carry on a complete configuration of the device with VP Control software ■ Replace the CPU board and Carry on a complete configuration of the device via VP Control software
Er65	Back light anomaly of LCD display	■ Replace the LCD
Er85	Impossible to start the secondary µ processor	■ Carry on a complete configuration of the device with VP Control software ■ Replace the CPU board and Carry on a complete configuration of the device via VP Control software
Er 16	■ Date / time failure	■ Check the date and the time clock ■ Replace the CPU board and Carry on a complete configuration of the device via VP Control software
Er56	■ Out put conditions / Step number association default	■ Carry on a complete configuration of the device with VP Control

Error codes	Meaning	Action
Er 17	■ Keyboard matrices default	■ Replace the keyboard ■ Check that there is no liquid presence inside the device which could damage keyboard and electronics boards
Er27	■ Keyboard matrices default	
Er37	■ ON/OFF key locked	
Er47	■ OFF key out of order (no way to switch OFF the device)	■ Replace the CPU board and carry on a complete configuration of the device via VP Control software
Er28	■ Language file incompatible	■ Carry on a complete configuration of the device via VP Control software

6 Intervention procedures

This chapter lists all the dismantling and re-assembling procedures.

N°1, Procedure: CPU board

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.)

Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump to its original position.

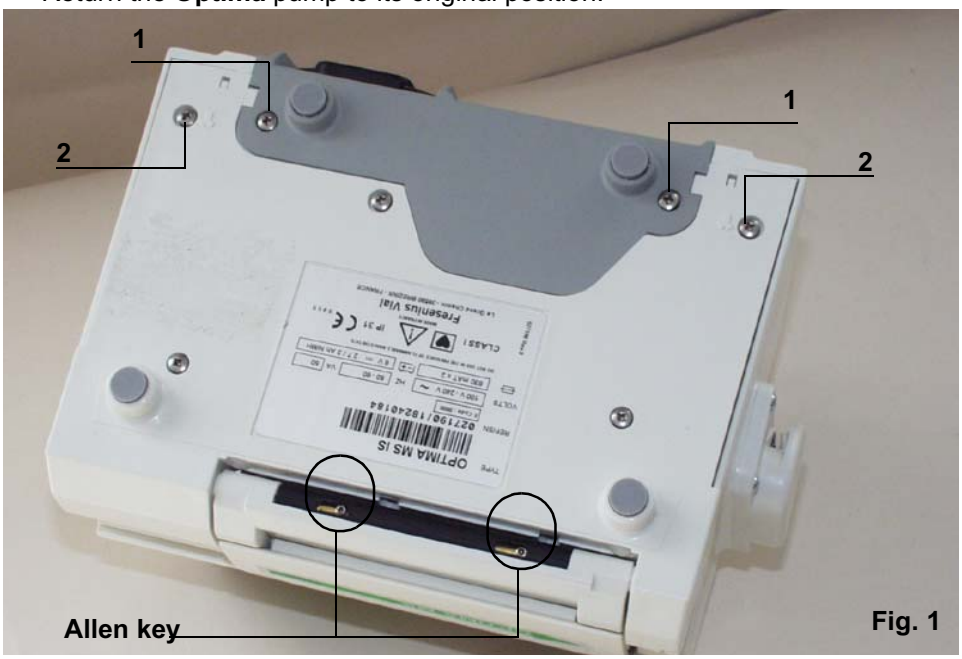


Fig. 1

- Using an Allen key, gently slide out the two screws located under the door.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.
- Remove the front cover, being careful not to pull out the CPU board flat cable.

- Disconnect the CPU board flat cable: J2 connector and J4 connector.

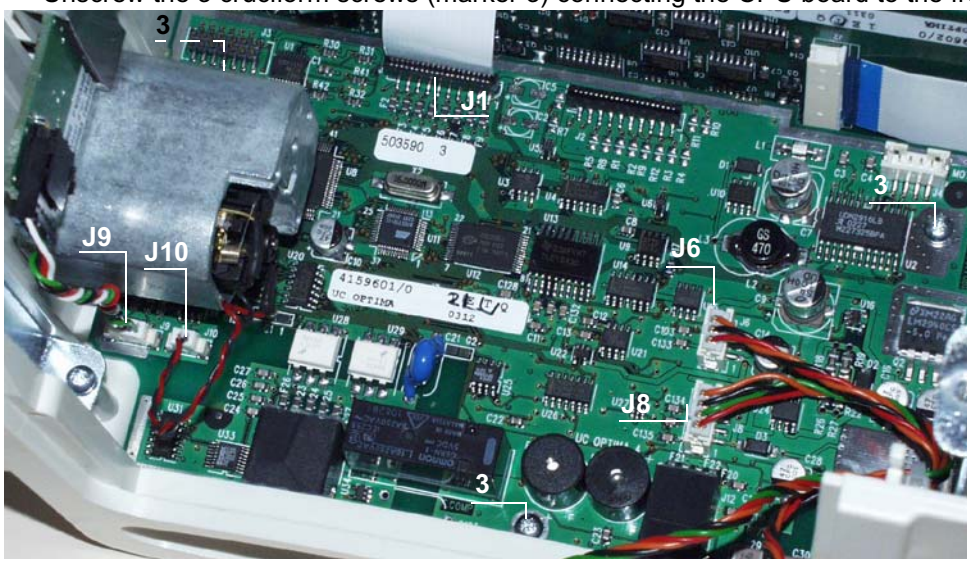
Fig. 2

Do not touch the electronic boards with your hands.

Dismantling

When working with electronic components, we recommend wearing an anti-static bracelet connected to the earth and working on a foam anti-static mat.

- Disconnect the J6, J8, J9 and J10 connectors.
- Disconnect the J1 flat cable.
- Unscrew the 3 cruciform screws (marker 3) connecting the CPU board to the front cover.



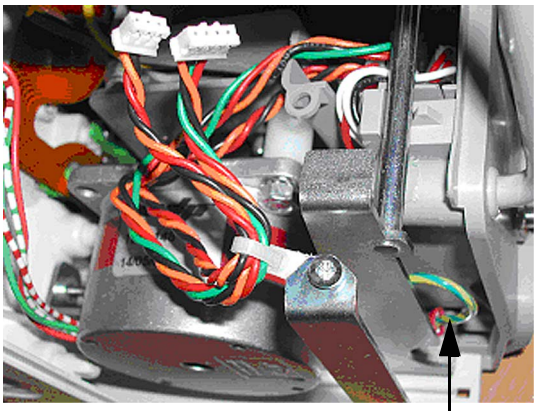
- Remove the board from its housing, being careful with the display board J3 flat cable.
- Remove the CPU board.

Re-assembling

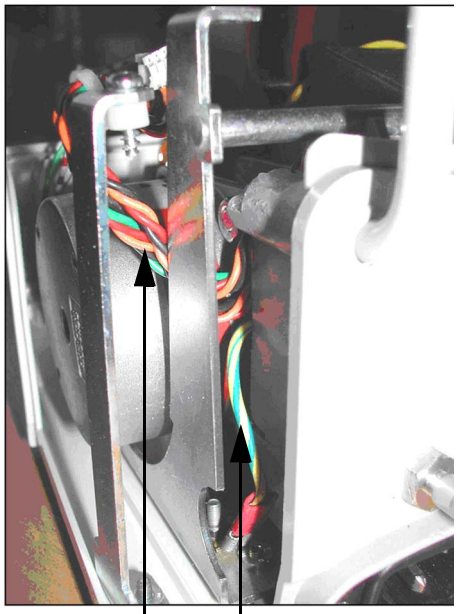
Carry out the dismantling procedure in reverse order to re-assemble the unit.

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation.

- Positioning of the earth wire.

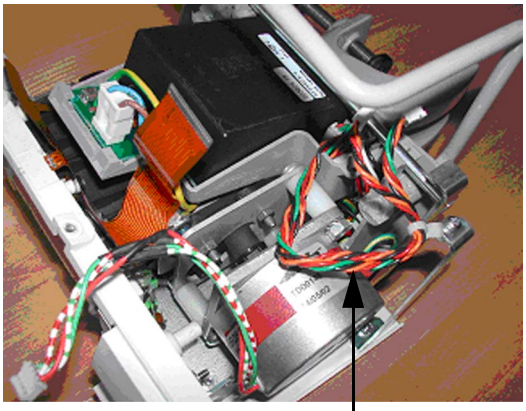


Correct

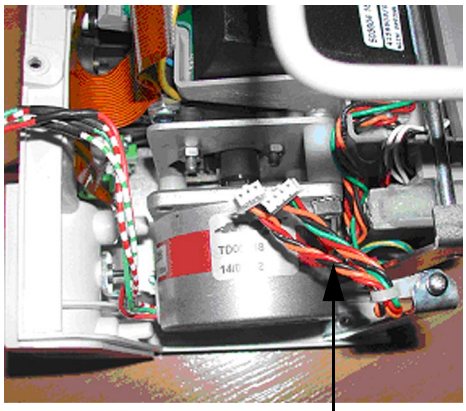


Incorrect

- Positioning of the wires connecting the power supply board and the CPU board.



Right



Wrong

Wrap an adhesive silicon cord around the CPU board J12 and J11 connectors.

■ Perform a complete configuration for a new board using VP Control Maintenance Software.

*Each **Optima** pump has its own type of "display and CPU board"; it is important that you do not mix up the different **Optima** pump references and that you order the one that corresponds to your device.*

■ Carry out regular servicing checks. (See Quality Control Certificate.)

N°2, Procedure: Display board

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

Level 2, specialist technician (see biomedical technical training documentation).

Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1) connecting the **Optima** pump angle bracket to the base.
- Remove the angle bracket, being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump back to its original position.

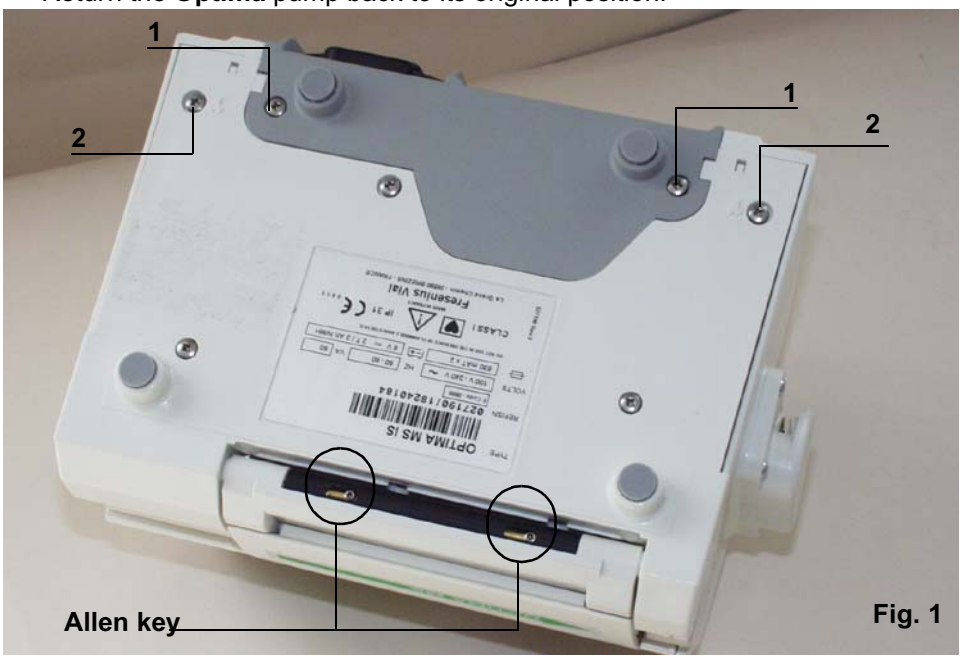


Fig. 1

- Using an Allen key, gently slide out the two screws located under the door.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.
- Remove the front cover, being careful not to pull out the CPU board flat cable.

- Disconnect the CPU board flat cable: J2 connector and J4 connector.

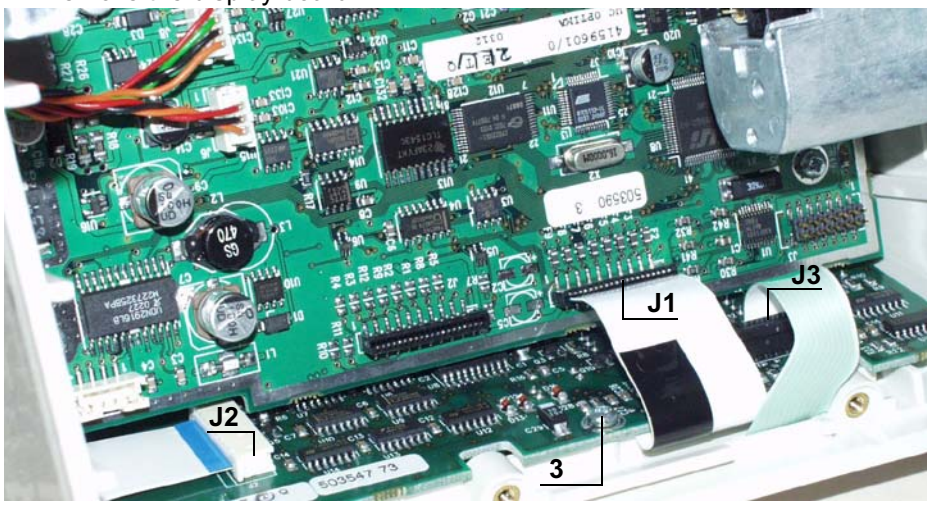
Fig. 2

Do not touch the electronic boards with your hands.

Dismantling

When working with electronic components, we recommend wearing an anti-static bracelet connected to the earth and working on a foam anti-static mat.

- Disconnect the J1 connector connecting the display board to the CPU board.
- Disconnect the display board J3 connector.
- Unscrew the cruciform screw (marker 3) situated on the display board, connecting it to the front cover.
- Remove the display board.



Re-assembling

*Each **Optima** pump has its own type of "display and CPU board"; it is important that you do not mix up the different **Optima** pump references and that you order the one that corresponds to your device.*

Carry out the dismantling procedure in reverse order to re-assemble the new unit.

When fixing the display board, ensure that the plastic inserts are not tightened too much or they will be damaged.
When positioning the front case, ensure that the sealing is perfectly positioned in its housing after re-assembling.

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. Also check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo on procedure sheet n°1.)

- Carry out regular servicing checks. (See Quality Control Certificate.)

N°3, Procedure: Pumping system

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.)

Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** pump angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump back to its original position.

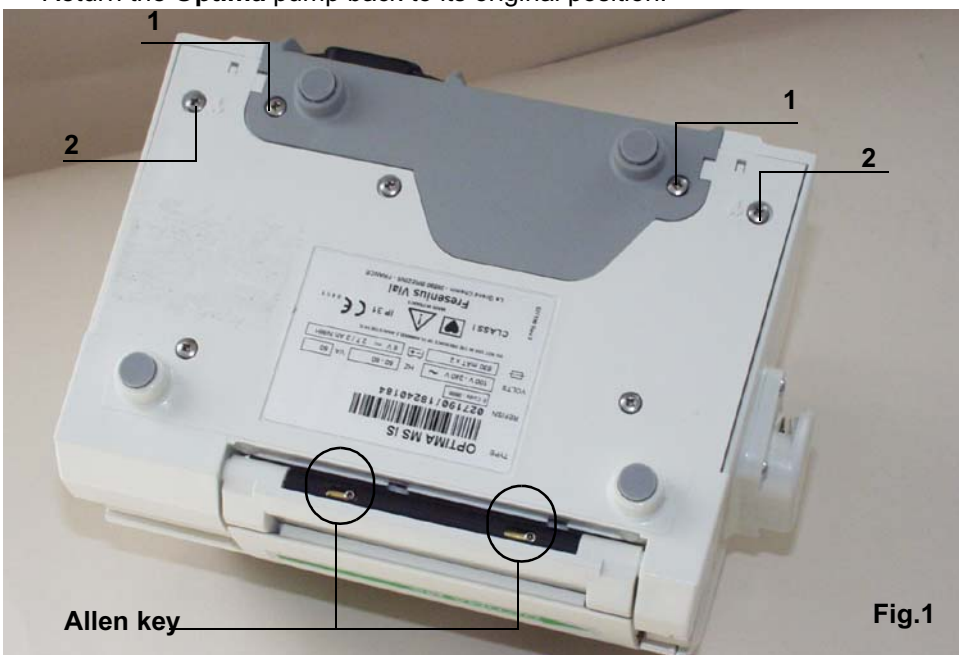


Fig.1

- Using an Allen key gently slide out the two screws located under the door from their groove.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.
- Remove the front cover, being careful not to pull out the CPU board flat cable.

- Disconnect the CPU board flat cable: J2 connector and J4 connector.

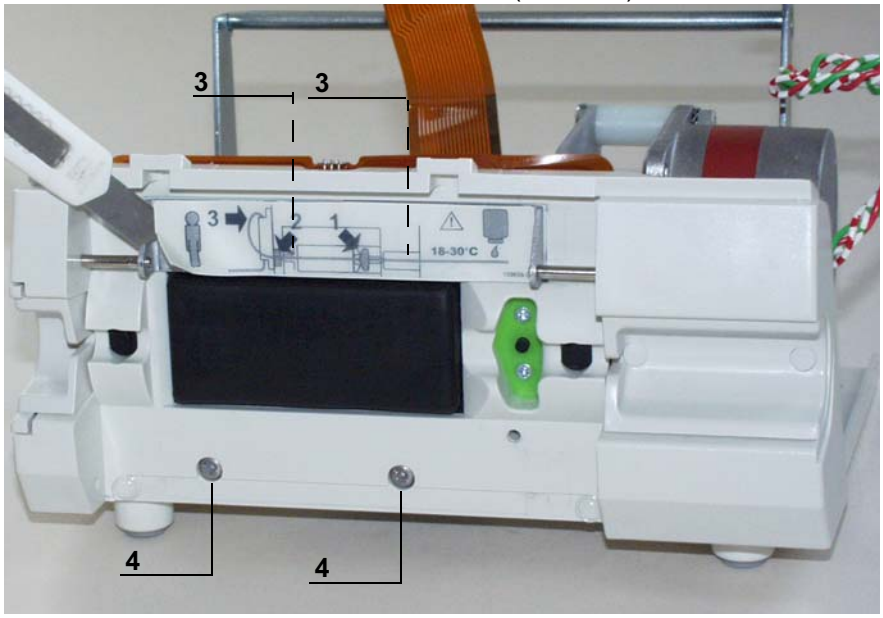
Fig.2

Do not touch the electronic boards with your hands.

Dismantling

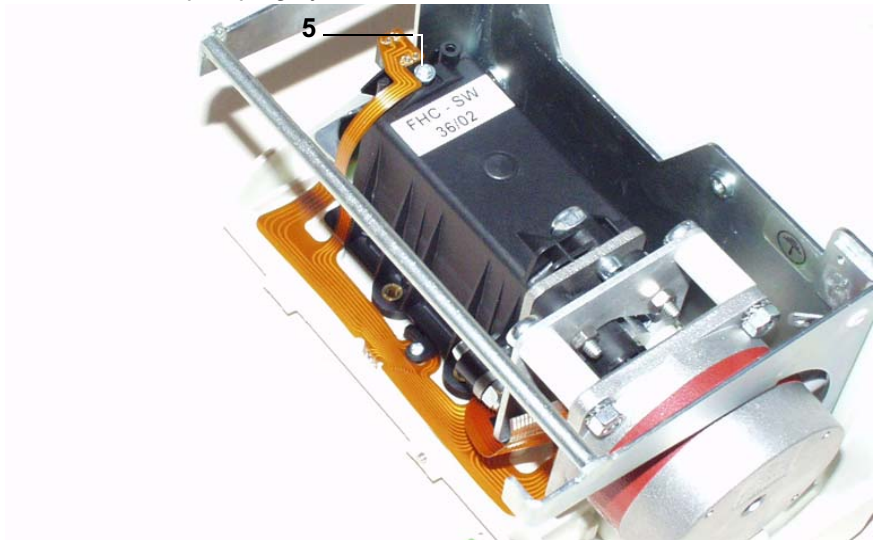
When working with electronic components, we recommend wearing an anti-static bracelet connected to the earth and working on a foam anti-static mat.

- Using a cutter, remove the label.
- Unscrew the 2 middle cruciform screws (marker 3) located under the label.



- Unscrew the 2 cruciform screws (marker 4).

- Unscrew the cruciform screw (marker 5), paying attention to the washer.
- Remove the pumping system.

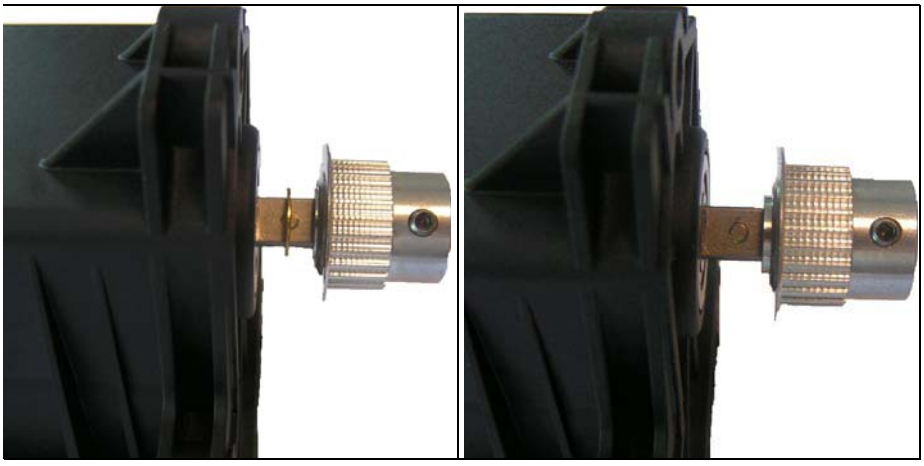


Re-assembling

When replacing the mechanical bloc, it's recommended to read the following instruction.

- If a good metal washer and a metal pulley are already mounted, let them in place.

old aluminium pulley with washer New aluminium pulley without washer



L

Check that there is no axial free play on the mechanical block cam shaft.

Carry out the dismantling procedure in reverse order to re-assemble the new unit.

When closing the pump ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo in Procedure n°1.)

- Carry out regular servicing checks. (See Quality Control Certificate.)

N°4, Procedure: LCD display

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.)

Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** pump angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump to its original position.

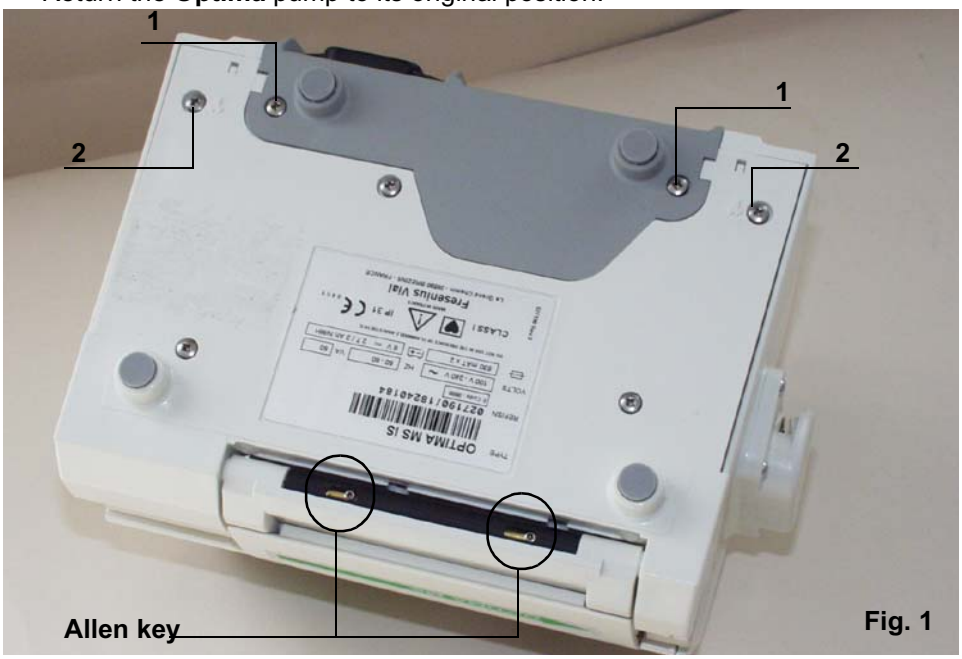


Fig. 1

- Using an Allen key, gently slide out the two screws situated under the door.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.
- Remove the front cover, being careful not to pull out the CPU board flat cable.

- Disconnect the CPU board flat cable: J2 connector and J4 connector.

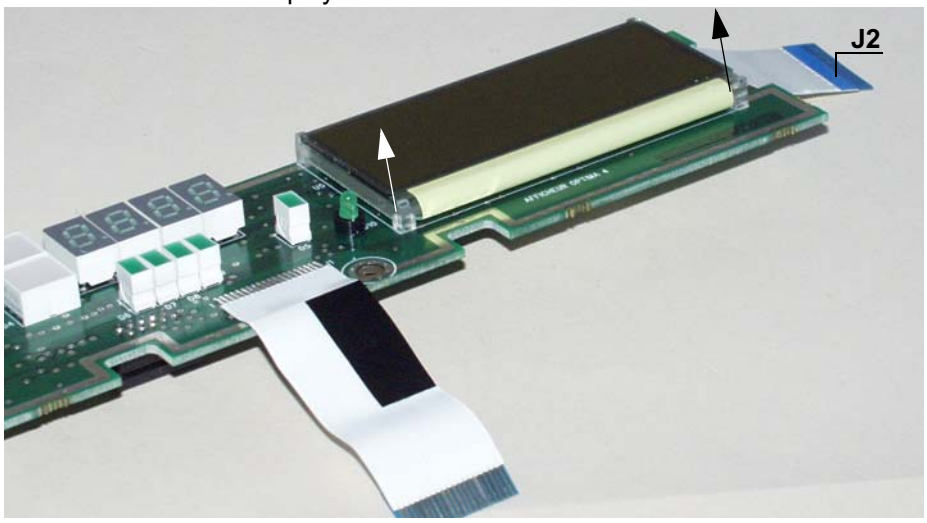
Fig. 2

Do not touch the electronic boards with your hands.

Dismantling

When working with electronic components, we recommend wearing an anti-static bracelet connected to the earth and working on a foam anti-static mat.

- Remove the display board. (See corresponding Procedure n°2.)
- Disconnect the J2 keyboard connector.
- Detach the LCD display.
- Remove the LCD display.



Re-assembling

- Recover the self-adhesive block from the old LCD.
- Position the self-adhesive block on the LCD display, above the LCD display label.
- Position the LCD display on the display board.
- Press down the display on the display board so that the block adheres to the display board.

Carry out the dismantling procedure in reverse order to re-assemble the new unit.

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo on Procedure n°1)

.

- Carry out regular servicing checks. (See Quality Control Certificate.)

N°5, Procedure: Air detector board

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.)

Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** pump angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump to its original position.

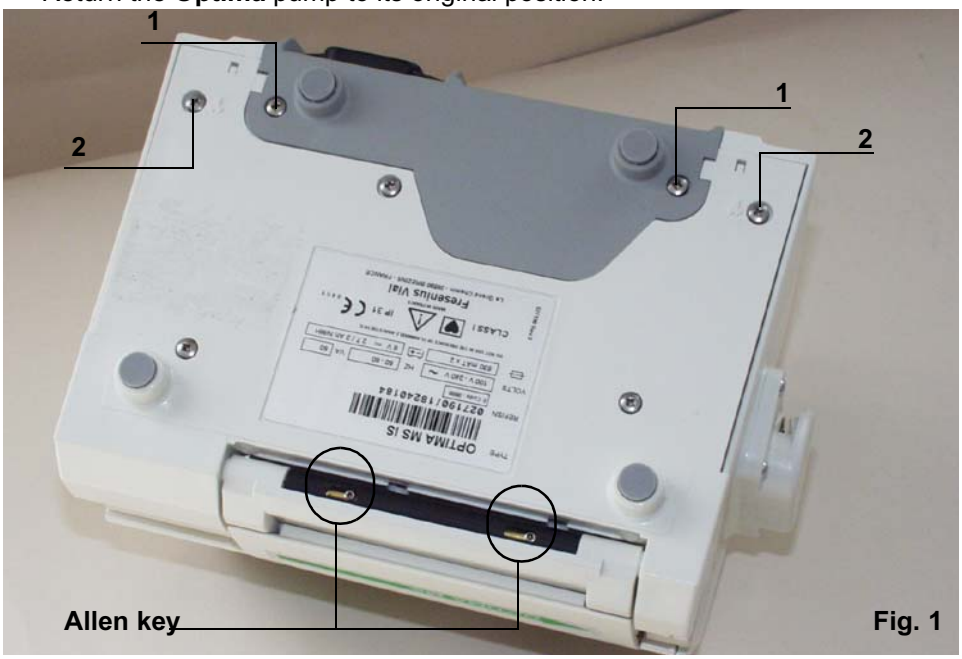


Fig. 1

- Using an Allen key, gently slide out the two screws located under the door.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.
- Remove the front cover, being careful not to pull out the CPU board flat cable.

■ Disconnect the CPU board flat cable: J2 connector and J4 connector.

Fig. 2

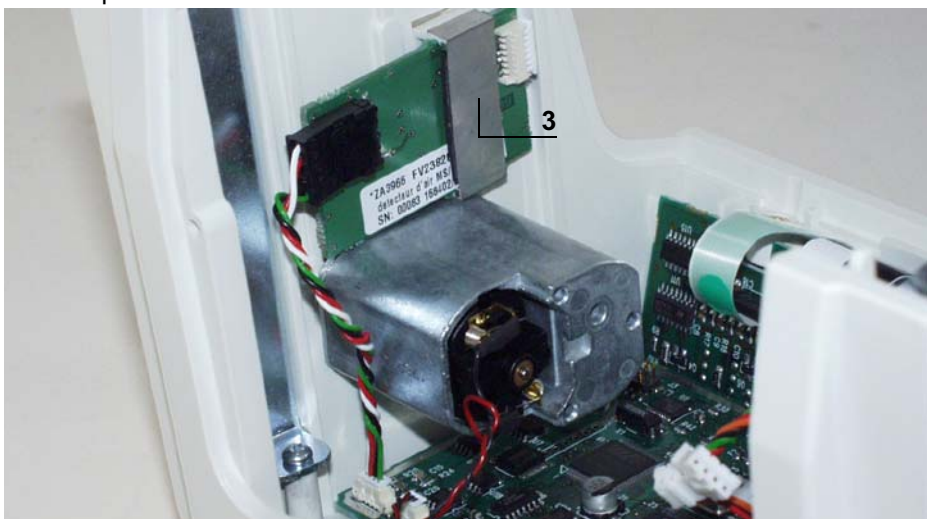
Do not touch the electronic boards with your hands.

Dismantling

When working with electronic components, we recommend wearing an anti-static bracelet connected to the earth and working on a foam anti-static mat.

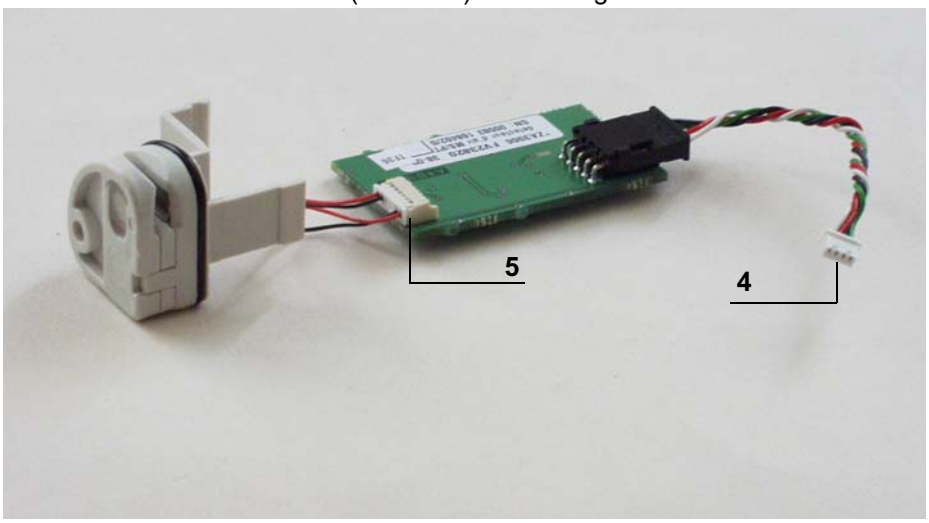
■ Unclip the non-oxidizing aluminium plate (marker 3) holding the air detector board in place.

■ Unclip the board.



■ Disconnect the J9 connector (marker 4) connecting the CPU board to the air detection board.

■ Disconnect the connector (marker 5) connecting the board to the air detector.



Re-assembling

Carry out the dismantling procedure in reverse order to re-assemble the new unit.

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support. Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo in Procedure n°1.) Carry out regular servicing checks.

■ Carry out regular servicing checks. (See Quality Control Certificate.)

N°6, Procedure: Pressure sensor

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.)

Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** pump angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump to its original position.

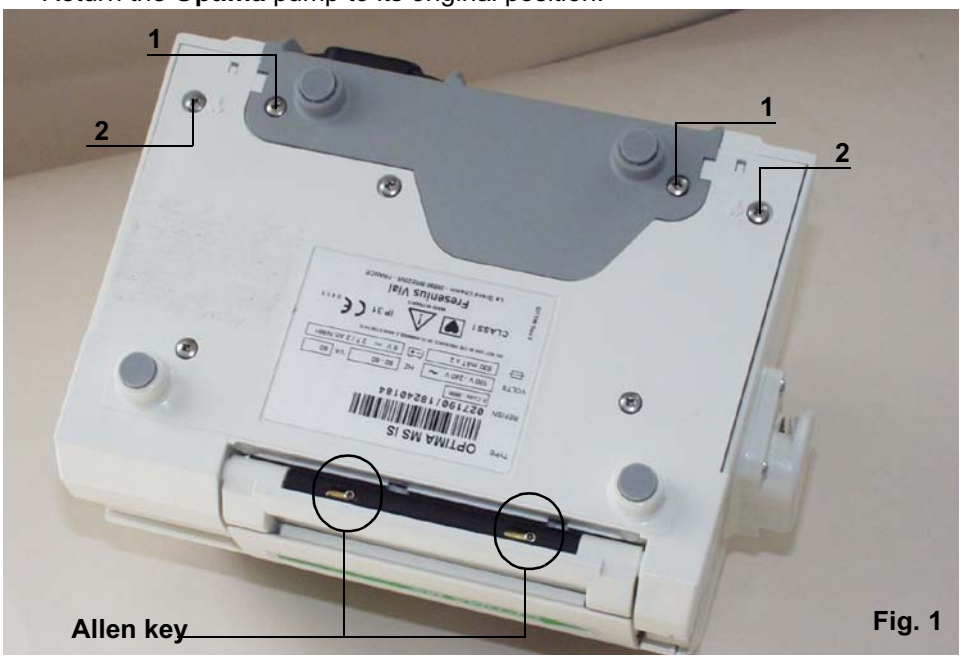


Fig. 1

- Using an Allen key, gently slide out the two screws located under the door.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.
- Remove the front cover, being careful not to pull out the CPU board flat cable.

- Disconnect the CPU board flat cable: J2 connector and J4 connector.

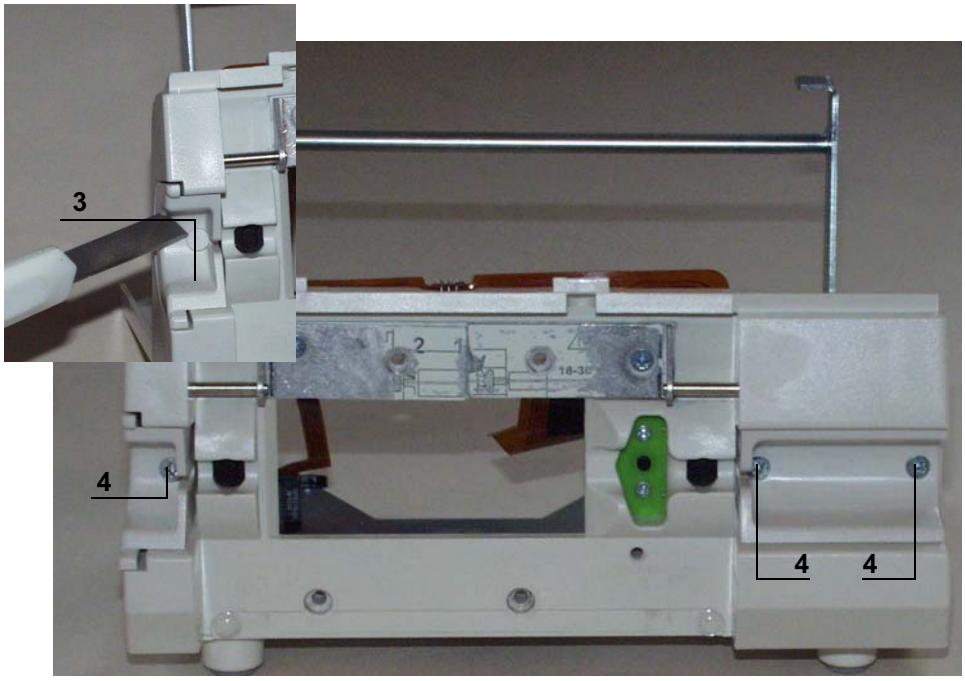
Fig. 2

Do not touch the electronic boards with your hands.

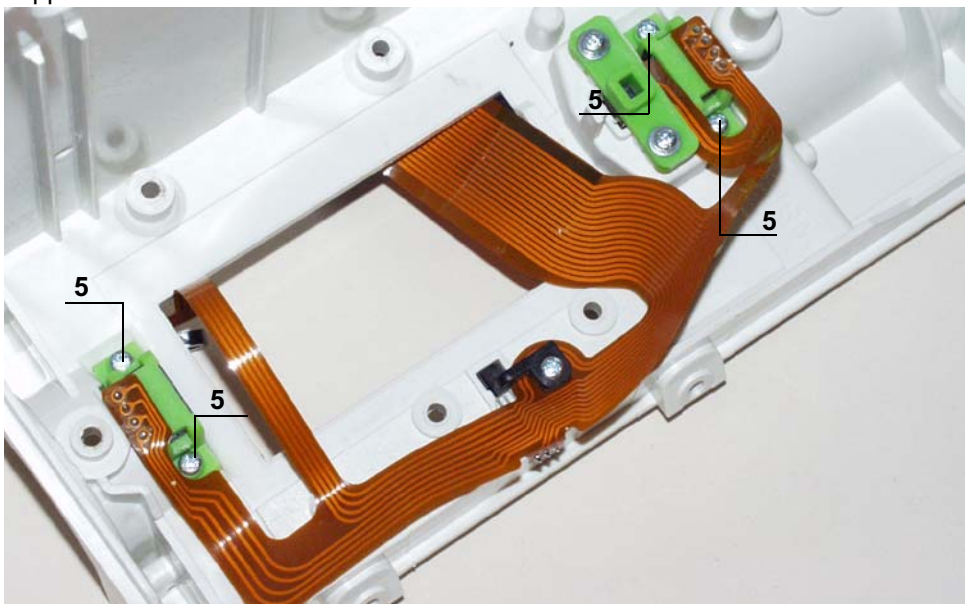
Dismantling

When working with electronic components, we recommend wearing an anti-static bracelet connected to the earth and working on a foam anti-static mat.

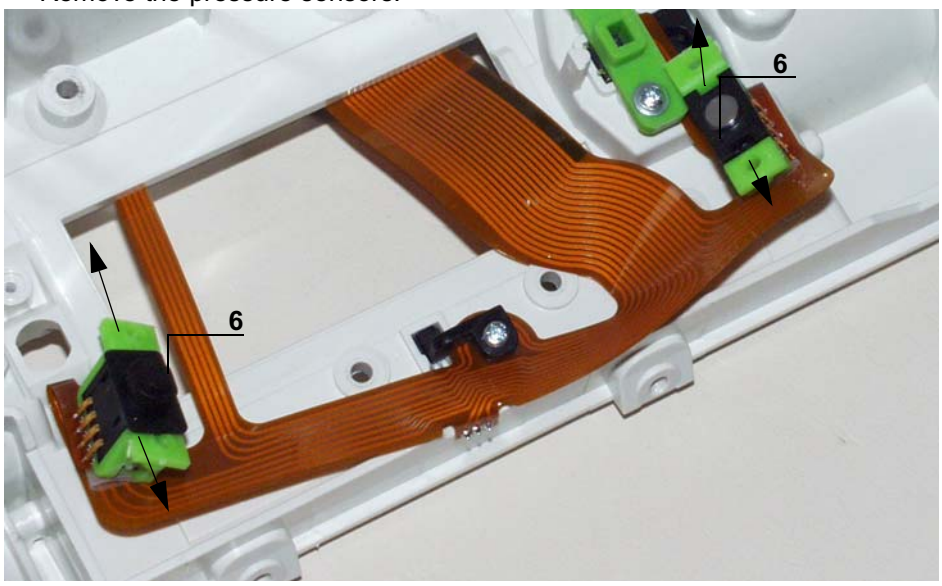
- Remove the pumping system. (See corresponding Procedure n° 3.)
- Using a cutter, unstick the "circular sticker" (marker 3).
- Unscrew the 3 cruciform screws (marker 4) situated under the "circular sticker" connecting the tube catches to the base.



- Remove the tube catchings.
- Unscrew the cruciform screw which maintain the right infusion set guide to the metallic plate and the base.
- Remove the plate.
- Unscrew the 2 screws of each pressure sensor support (marker 5) connecting the supports to the base.



- Separate the pressure sensors from their support (see arrows)
- Unsolder the pressure sensor wires (marker 6).
- Remove the pressure sensors.



Re-assembling

Carry out the dismantling procedure in reverse order to re-assemble the unit.

After re-assembling the pressure sensors, calibrate them. (See **ETAL 9**, *Calibrating the upstream and downstream pressure sensors.)*

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo in Procedure n°1.)

- Carry out regular servicing checks. (See Quality Control Certificate.)

N°7, Procedure: OCS clamp motor (if OCS is present)

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.)

Procedure

Access

- Pivot the **Optima** pump over the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump to its original position.

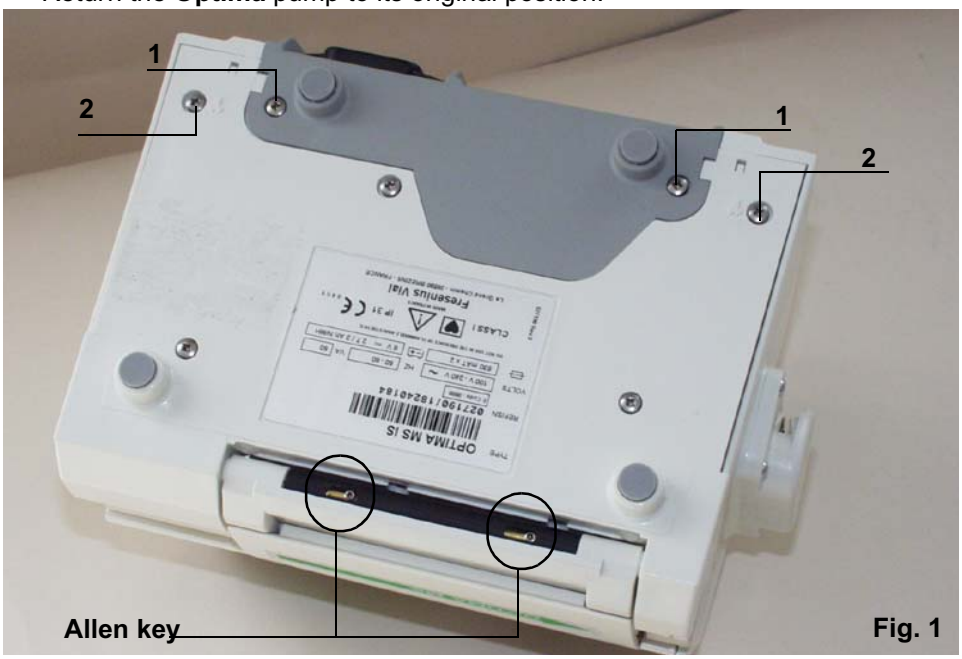


Fig. 1

- Using an Allen key, gently slide out the two screws located under the door.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.
- Remove the front cover, being careful not to pull out the CPU board flat cable.

- Disconnect the CPU board flat cable: J2 connector and J4 connector.

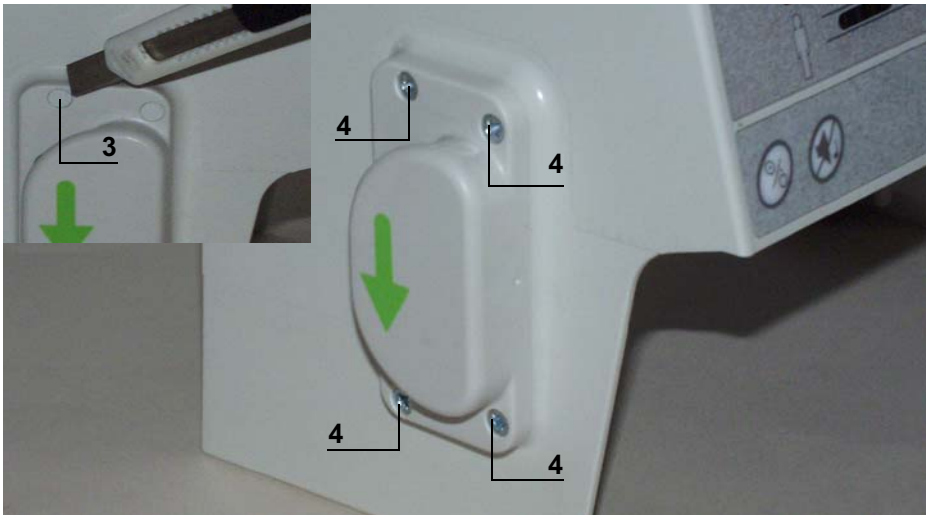
Fig. 2

Do not touch the electronic boards with your hands.

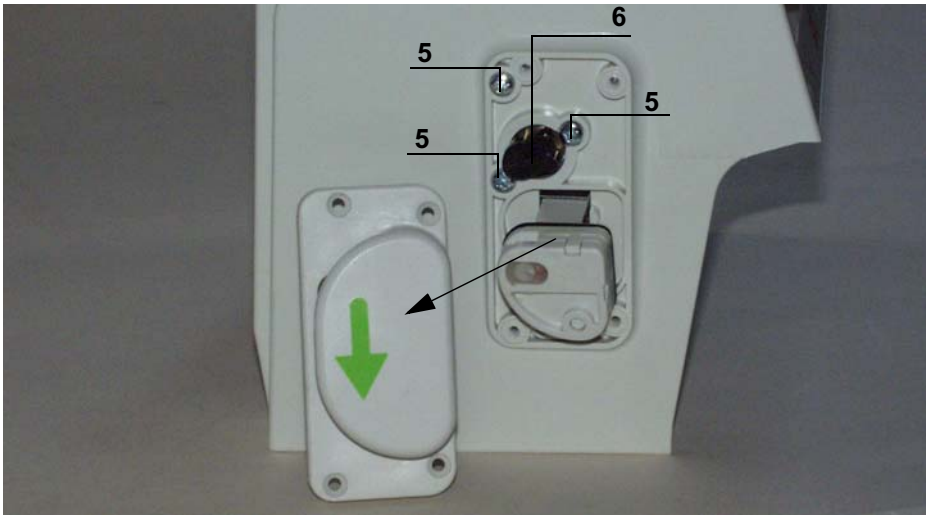
Dismantling

When working with electronic components, we recommend wearing an anti-static bracelet connected to the earth and working on a foam anti-static mat.

- Using a cutter, unstick the 4 "circular stickers" (marker 3).
- Unscrew the 4 cruciform screws (marker 4) situated under the "circular stickers", holding the air bubble detector case to the front cover.



- Separate the air detector from the case.
- Disconnect the J10 connector (CPU board).
- Unscrew the clamp (marker 6), while holding the motor reducer.
- Unscrew the 3 cruciform screws (marker 5) holding the motor reducer to the front cover.
- Remove the motor reducer.



Re-assembling

Carry out the dismantling procedure in reverse order to reassemble the unit.

When re-assembling the motor clamp, apply a drop of silicon grease around the screw path (marker 6).

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo in Procedure n°1.)

.

- Carry out regular servicing checks. (See Quality Control Certificate).

N°8, Procedure: Power supply board

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet

Maintenance level:

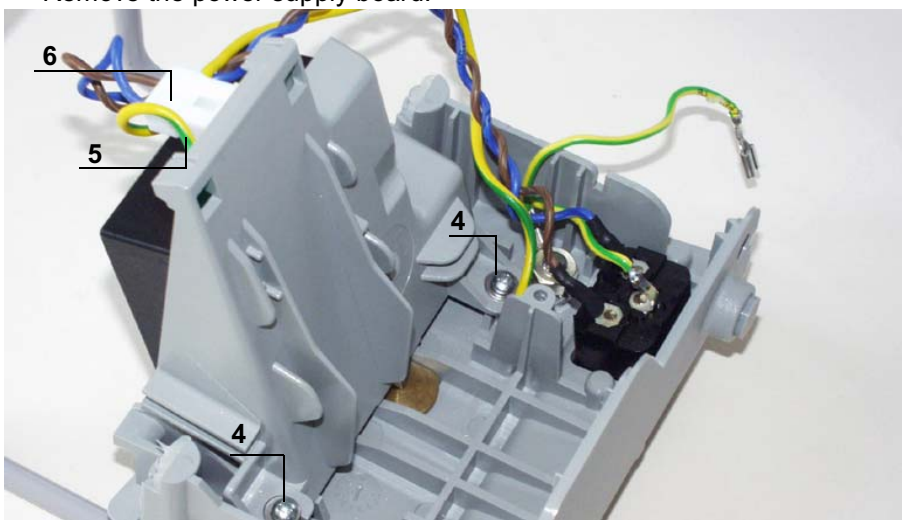
Level 2, specialist technician. (See biomedical technical training documentation.)

Procedure

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** pump angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.

- Unscrew the 2 cruciform screws (marker 4) holding the power supply shelf in place.
- Disconnect the earth wire (marker 5) and the mains connector (marker 6).
- Remove the power supply board.



Re-assembling

Carry out the dismantling procedure in reverse order to re-assemble the unit.

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo in Procedure n°1.)

- Carry out regular servicing checks. (See Quality Control Certificate.)

.

N°9, Procedure: Battery

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed:

- 1 Posidriv Z1 screwdriver

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.)

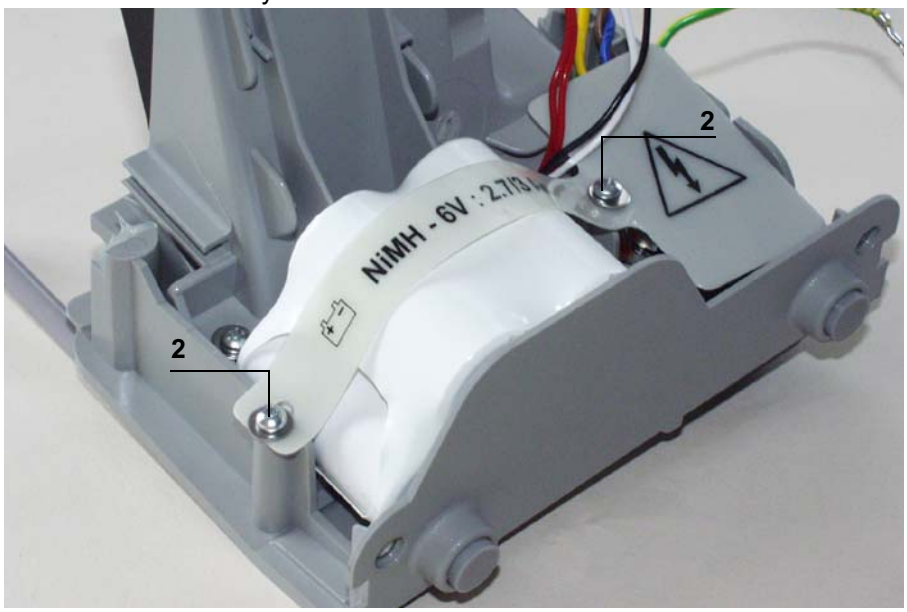
Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1) connecting the **Optima** pump angle bracket to the base.
- Remove the angle bracket, being careful not to pull out the connectors.

Dismantling

- Unscrew the 2 cruciform screws (marker 2) holding the battery in place.
- Disconnect the battery.
- Remove the battery.



Re-assembling

Carry out the dismantling procedure in reverse order to re-assemble the unit.

We recommend carrying out a complete charging and discharging cycle to guarantee that the battery will function correctly.

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo in Procedure n°1.)

- Carry out regular servicing checks. (See Quality Control Certificate.)

N°10, Procedure: Front cover, base and angle bracket

Safety:

For safety reasons, the technician should not intervene while the device is in operation.

Material needed

- 1 Posidriv Z1 screwdriver
- 1 anti-static bracelet
- 1 soldering iron
- Soldering wire "RADIEL Sn60Pb RI 1" (no cleaning necessary) or equivalent

Maintenance level:

Level 2, specialist technician. (See biomedical technical training documentation.).

Procedure:

Access

- Pivot the **Optima** pump on the top of the front cover.
- Unscrew the 2 cruciform screws (marker 1), connecting the **Optima** angle bracket to the base.
- Remove the angle bracket being careful not to pull out the connectors.
- Disconnect the J4 and J3 connectors, as well as the functional Earth.
- Return the **Optima** pump to its original position.

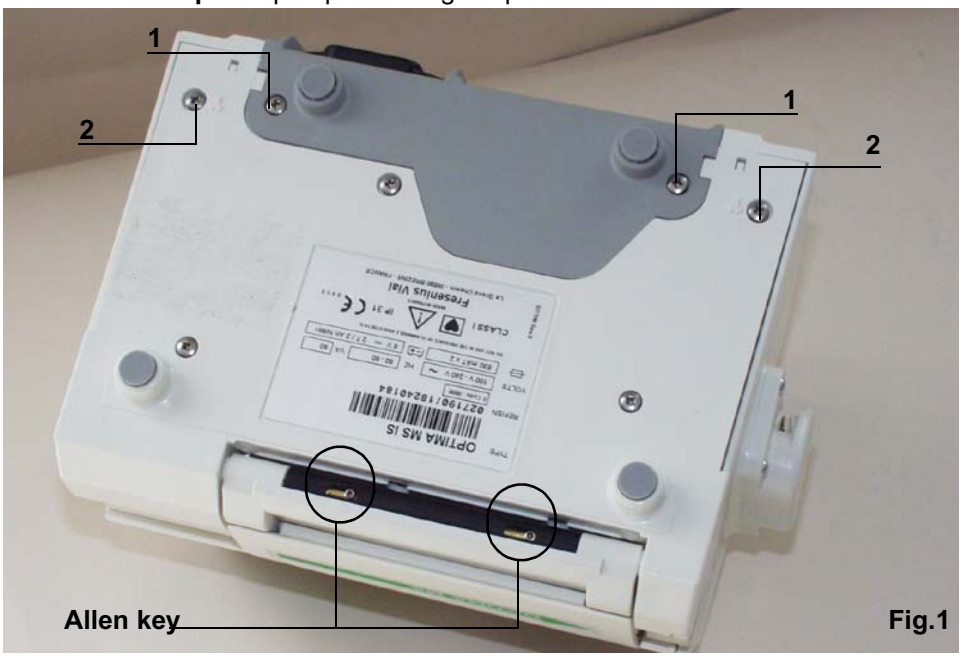


Fig.1

- Using an Allen key, gently slide out the two screws located under the door.
- Remove the door.
- Unscrew the 4 cruciform screws (marker 2 on Fig. 1 and 2) connecting the front cover to the base.

- Disconnect the CPU board flat cable: J2 connector and J4 connector.

Fig.2

Do not touch the electronic boards with your hands.

Dismantling the upper cover

- Dismantle the CPU board. (See corresponding Procedure.)
- Dismantle the display board. (See corresponding Procedure.)
- Dismantle the OCS motor clamp. (See corresponding Procedure.)
- Dismantle the air detector board. (See corresponding Procedure.)

Re-assembling the upper cover

- Re-assemble the display board. (See corresponding Procedure.).
- Re-assemble the CPU board. (See corresponding Procedure.)
- Re-assemble the OCS motor clamp. (See corresponding Procedure.)
- Re-assemble the air detector board. (See corresponding Procedure.)

Dismantling the base

- Dismantle the pumping system. (See corresponding Procedure.)
- Dismantle the tube clamp switch. (See corresponding Procedure.)
- Dismantle the pressure sensors. (See corresponding Procedure.)

Re-assembling the base

Carry out the dismantling procedure in reverse order to re-assemble the base.

Dismantling the angle bracket

- Dismantle the battery. (See corresponding Procedure.)
- Dismantle the power supply board. (See corresponding Procedure.)

Re-assembling the angle bracket

Carry out the dismantling procedure in reverse order to re-assemble the angle bracket.

When closing the pump, ensure that the 2 cables connecting the power supply board and the CPU board are positioned above the motor. In addition, check that the earth wire is next to the metal support.
Incorrect positioning of one of these cables could result in a noise being heard when the pump is in operation. (See photo in Procedure n°1.)

- Carry out regular servicing checks. (See Quality Control Certificate.)

7 Calibration

7.1 Calibration procedure

The calibration menu is reserved for qualified staff only. Its access is protected with a secret code.

7.1.1 Access to the calibrations

Keyboard description.

Key	Function
	ON switches on the device. **OFF** switches off the device when pressed for more than three seconds.
	SILENCE ALARM
	START validates a choice.
	MODE accesses the calibrating mode.
	The selection keys scroll through the numbers and letters on the LCD screen using the tenths, units and tens values. Activate or de-activate the infusion menu.
	ENTER confirms the selected calibration, or moves the cursor.
	STOP cancels the current calibration.

How to activate the calibration mode

- Keep the "MODE" button pressed, during the device switch on.
  - ☐ The various menus are displayed.

- Using the selection keys, select "Maintenance" on the display.
- Press "START".

- Key in the access code.
- Press "START".

- Select "Calibration".Press "START".

- Using selection keys select:
  - ☐ CAL.1: calibration of the door.
  - ☐ CAL.2: calibration of the infusion flow rate corrective coefficient.
  - ☐ CAL.9: calibration of the upstream and downstream pressure sensors.

7.1.2 EtAL.1 Door calibration

This menu records the 3 door positions in the EEPROM.

■ EtAL.1, press "START".

□ Por.1: close the door without tube.

- Press "START".
  The value is read and recorded. The value should be between
  1196 < X < 3750 mV.

□ Por.2: open the door without tube.

- Press "START".
  The value is read and recorded. The value should be between
  2197 < X < 2695 mV.

□ Por.3: position a tube filled with water and close the door.

- Press "START".
  The value is read and recorded. The value should be between
  1699 < X <3398 mV.

□ By validating once again, another calibration can be selected.

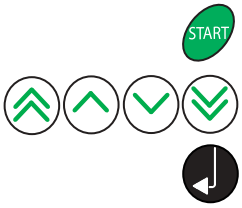
Press "STOP" key to exits the menu without memorising the calibration values.

7.1.3 CAL.2 Calibration of the flow rate corrective coefficient

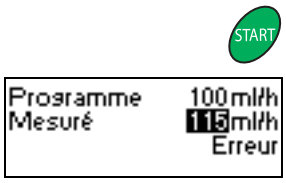
Before any flow rate test, carry out an infusion of 20 ml to stabilise the flow rate. The adjustment range allows a correction up to -10% to +10%.

This menu adjusts the device flow rate according to the used tube.

- Place a tube filled with water on the device, taking into account the positioning of the clamp, and close the door.
- Select a flow rate of 100 ml/h.
- Start the infusion.
- Perform a flow rate measurement according to the norm 601-1-2-24.
- Note the programmed flow rate and the obtained flow rate.
- CAL.2, press "START".



  - Using the selection keys, enter the programmed flow rate.
  - Press the "ENTER" key to move from one field to another.
  - Enter the measured flow rate.
  - Press "START" to start the calculation of the new corrective coefficient.
    - if the coefficient lies between 0.9 and 1.1, you may return to the configuration menu.
    - if the coefficient does not lies between 0.9 and 1.1 the "Error" message appears.



Pressing "STOP" exits the menu without calculating the new coefficient.

7.1.4 ETAL.9 Calibrating the upstream and downstream pressure sensors

This menu records the pressure value in the EEPROM according to the selected tube.

The **Optima** can operate with various tube types. The choice of tube is made through:

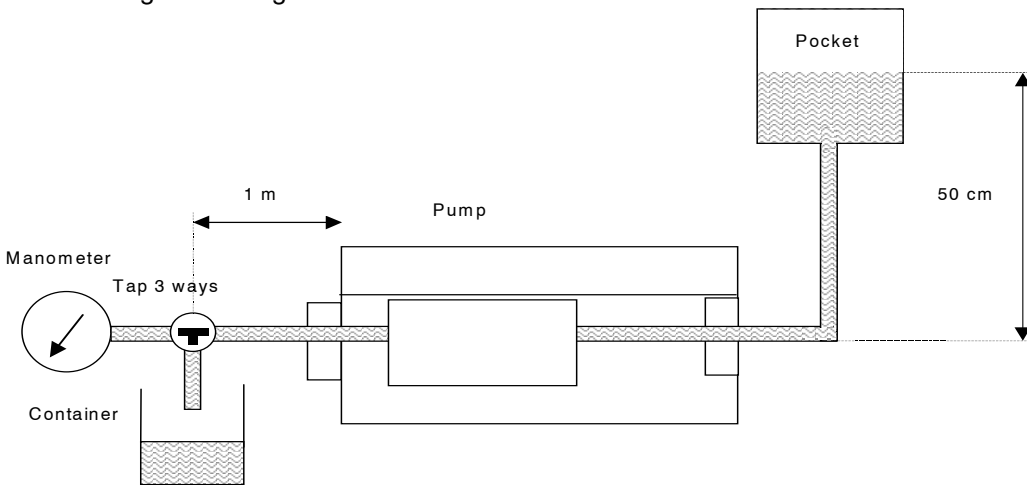
- the "MODE" key, set selection when the pump is on normal mode.
- maintenance menu and SAV 2

The pressure calibration must be done for each type of tube active on the pump.

If a pressure sensor, the door sensor or CPU board has been changed, the calibration values must be reset to zero for each tube. Where the CPU board has been changed, the calibration must be carried out using maintenance software during the configuration procedure.

Installation:

- According to the diagram below:



*The manometer must be placed at the same level as the **Optima** pump.*

■ CALIB.9, press "START".

Resetting the pressure calibrations

- ☐ Choose "YES" or "NO" using the selection keys and confirm.
- ☐ If "YES", the calibration values for the pressure sensors are reset to zero, for all tubes.
- ☐ If "NO", the calibration values are reset to zero only for the tube selected.

If the calibration of the pressure sensors should be performed only for the tube selected, it's recommennded to choose "NO".

When choosing "YES" a calibration for all the tubes programmed should be carried out using VP control maintenance sofware.

When changing the force sensors, the calibration should be done for all the tube available on the pump.
The calibration described below is concerns only the active tube chosen through mode key / set selection or maintenance / SAV 2.

- ☐ Press "CONFIRM" key to start the calibration.

Calibrating the downstream and upstream pressure sensor with the door open.

- ☐ PAU.1,PAN.1: open the door of the **Optima** pump, no tube installed.

- ☐ Press "ENTER".

- The values for "downstream pressure sensor door open" and "upstream pressure sensor door open" are read and recorded.
- The threshold for "downstream pressure door open" must be between 1997 < X < 4453 mV.
- The threshold for "upstream pressure door open" must be between 1197 < X < 4297 mV.

Calibrating the downstream pressure sensor at 0 mm Hg with the door closed, filled tube installed.

- ☐ Position the tube according to the preceding diagram and open the 3-channel tap in the direction of the Pump-Manometer.
- ☐ Press "START", to warm up the tube.
- ☐ Wait until the pressure reaches around 750 mm Hg (1 bar +/- 0.05 bar), and open the 3-channel tap in the pump-container direction to lower the pressure (0 mm Hg).
- ☐ Press "STOP" to stop infusion.
- ☐ Press "ENTER" to record the pressure.

- The threshold for the "downstream pressure at 0 mm Hg door closed" should be between 1499 < X < 3696 mV.

Calibrating the downstream pressure sensor at 750 mm Hg with the door closed filled tube installed.

- ☐ Position the 3 channel tap in the direction pump-manometer.
- ☐ Press "START" to start up the pump.
- ☐ Wait until the pressure reaches 750 mm Hg ±30 mm Hg (1 bar +/- 0.05 bar).
- ☐ Press "STOP" to stop infusion.
- ☐ Press "ENTER" to record the pressure value.

- The threshold for "downstream pressure at 750 mm Hg door closed" should be between 898 < X < 2998 mV.

Calibrating the upstream pressure sensor at 0 mm Hg with the door closed filled tube installed.

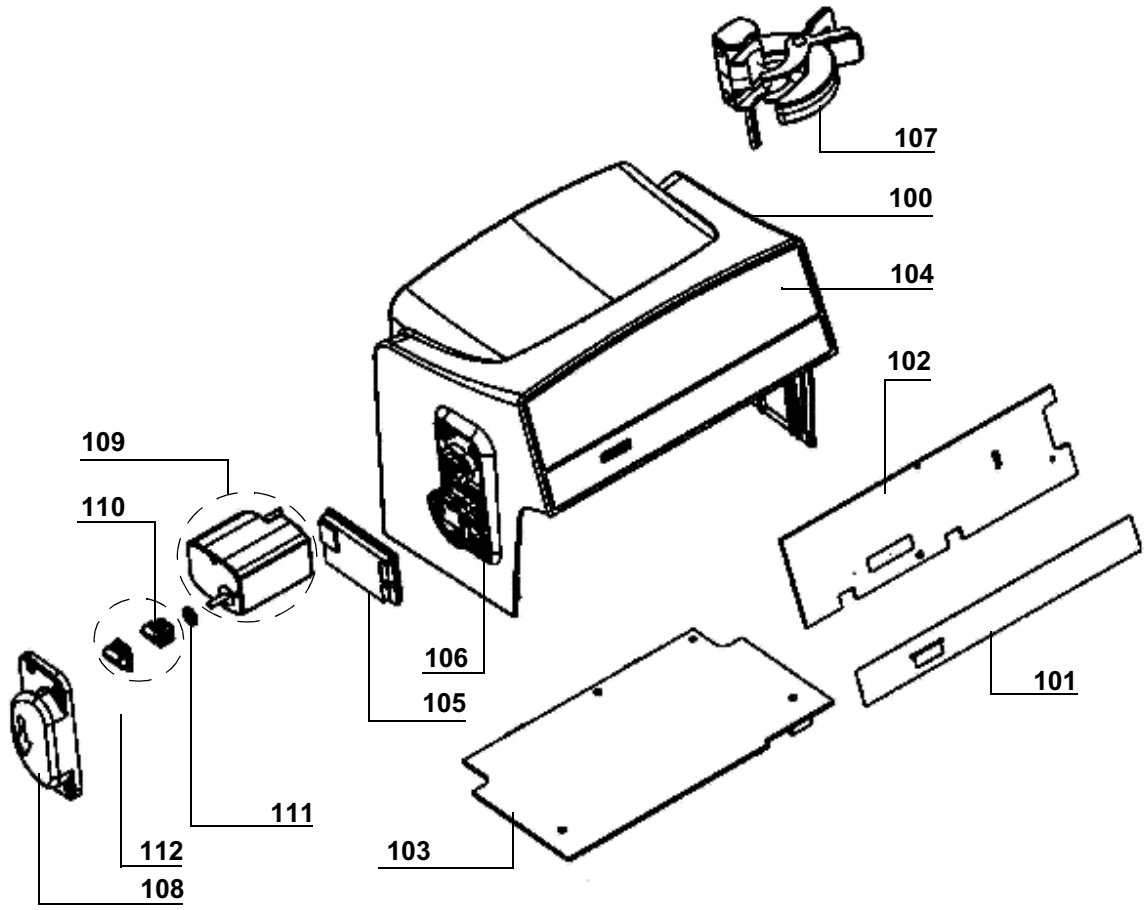
- ☐ Keep the door closed.
- ☐ Open the 3-channel tap in the direction pump-container.
- ☐ Press "ENTER" to record the pressure, when the pressure level is back to 0 mm Hg.

- The threshold for "upstream pressure at 0 mm Hg door closed" should be between 1499 < X < 3696 mV.

Press "STOP" key to exit the menu without memorising the calibration values.

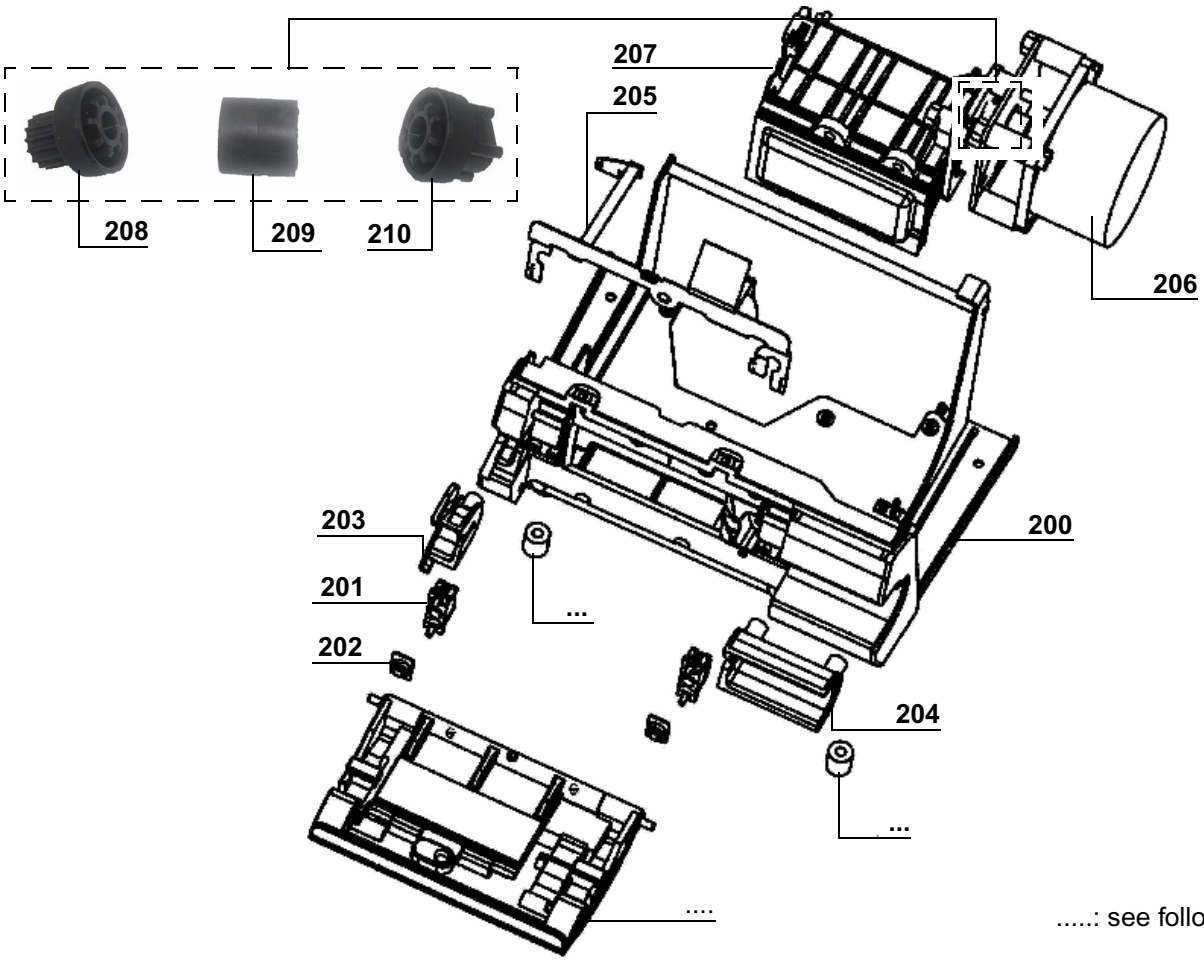
8 Spare parts catalogue

8.1 Upper cover



Marker	Qty	Reference	Name
100	1	159611	Upper cover
101	1	159620	Keyboard
102	1	159602	Display board
103	1	159605	CPU board
104	1	159616	Window
105	1	168402	Air detection board PT/VS
105	1	168403	Air detection board ST
106	1	168938	Air detector
107	1	159899	Drip detector
108	1 1	168765 174253	Air detector cover Sealing
109	1	159646	OCS motor reducer (only on **Optima VS**)
110	1 1 1 1	168349 168487 168348 199623	Clamp (only on **Optima VS**) Motor reducer washer Clamp screw Truarc ring
111	1	174256	OCS O ring (only on **Optima VS**)
112	1	168448	Clamp cap (**Optima PT-ST**)

8.2 Base



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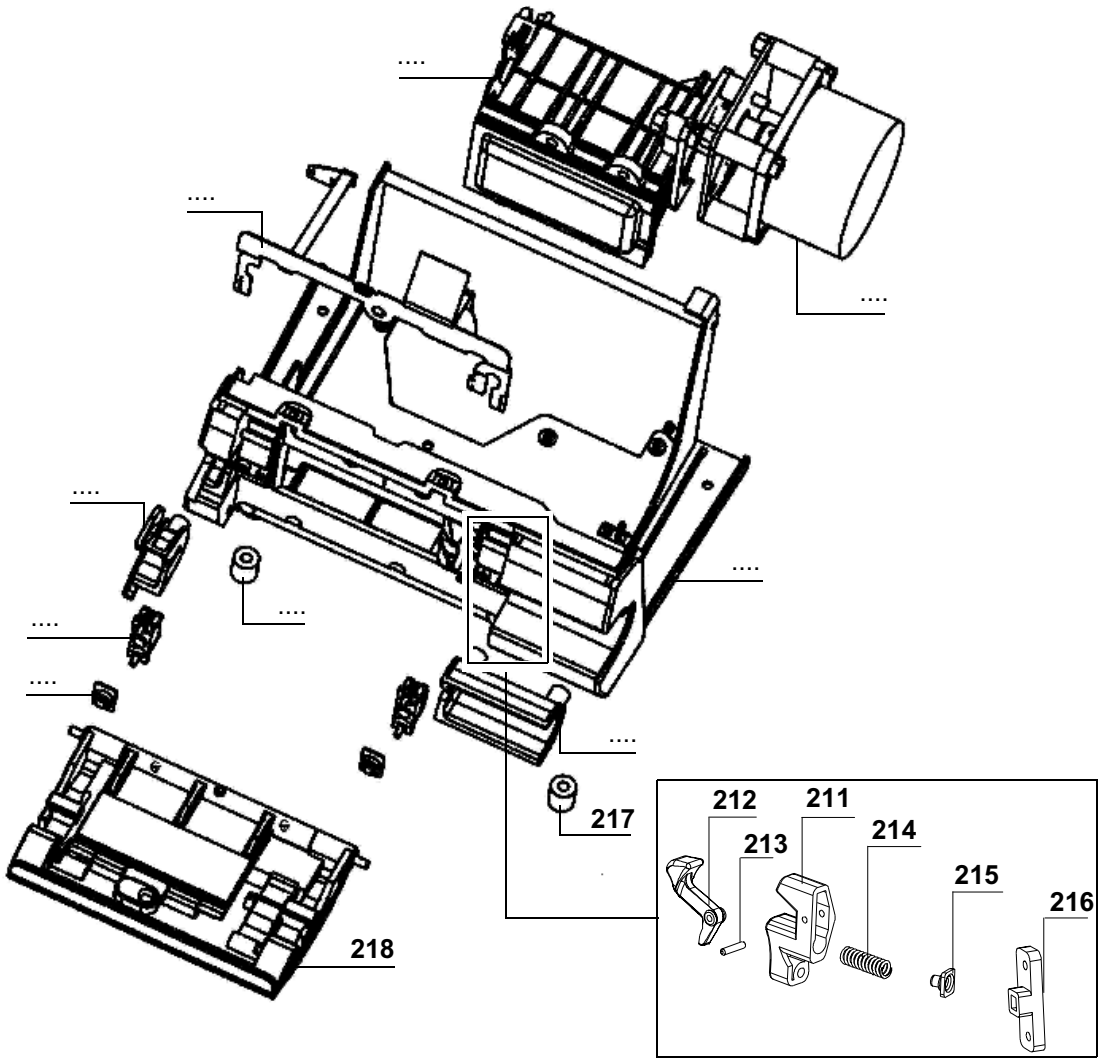
Marker	Qty	Reference	Name
200	1	159610	**Optima** pump base
201	2	168480	Pressure sensor
	2	168428	Sensor clip
202	2	168439	Sensor membrane
	1	651211	Pumping system membrane
203	1	159621	Left tube guide (**Optima PT-VS**)
203	1	168435	Left tube guide (**Optima ST**)
204	1	168437	Right tube guide (**Optima PT-VS**)
204	1	168438	Right tube guide (**Optima ST**)
205	1	159604	Flexible circuit
206	1	159648	Motor
207	1	168479	Mechanical bloc
	1	159679	Pump pulley
	1	191156	Washer
	1	168482	Belt
208	1	168497	INCA pin block
209	1	168498	Shock absorber
210	1	168379	Flask motor tube

Spare parts catalogue



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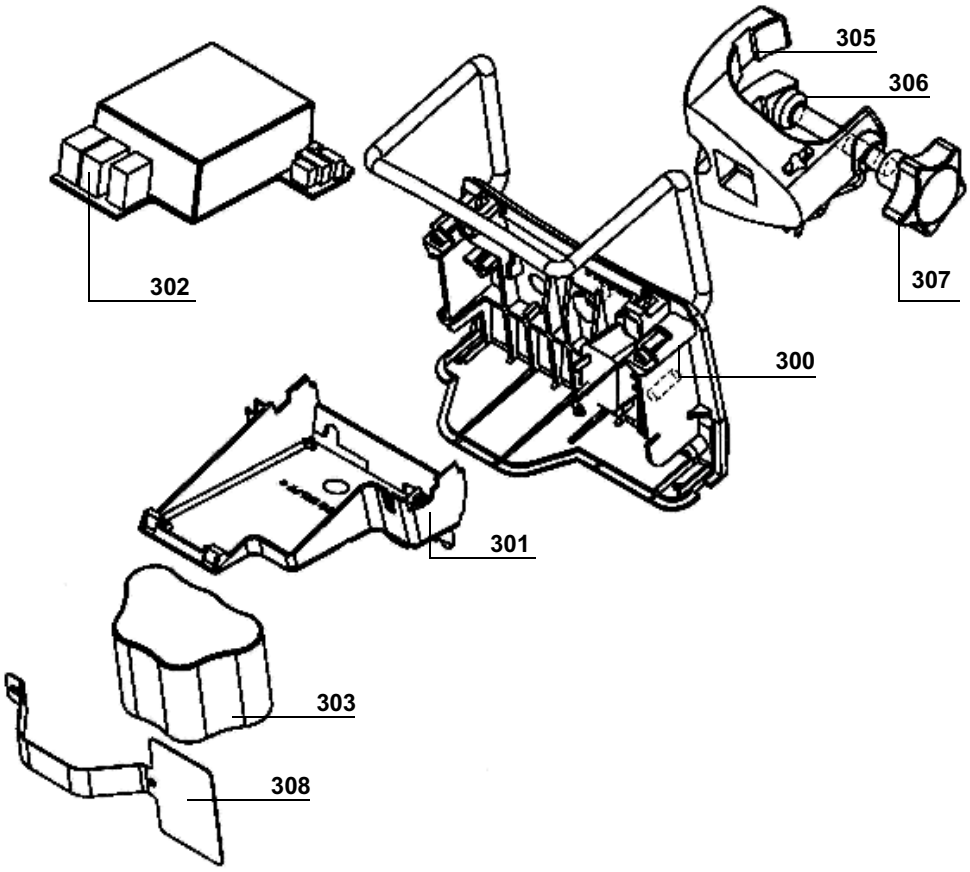
Marker	Qty	Reference	Name
211		168427	Clamp sleeve
212	1	168426	**Optima PT-VS** guillotine
212	1	168441	**Optima ST** guillotine
213	1	168460	Clamp shaft
214	1	168456	Clamp spring
215		168440	Membrane switch
216		168456	Clamp spring
	1	159659	**Optima PT-VS** bracket label
	1	159660	**Optima ST** bracket label
217	2	159618	Feet
218	1	199276	**Optima PT-VS** door kit
218	1	199277	**Optima ST** door kit

8.3 Optima pump angle bracket



Marker	Qty	Reference	Name
300	1	199273	**Optima** angle bracket kit
301	1	159613	**Optima** shelf
302	1	159608	Power supply board
303	1	159622	Battery pack
	2	159618	Foot
304	1	159617	Handle
305	1	159639	Fixing nut
	1	159627	Fixing nut insert catch
	1	174255	Nut ring seal
306	1	182108	Handle screw end sleeve
307	1	159643	Clip-on M8 screw end
308	1	159623	Battery clamp

Spare parts catalogue

Useful addresses

SALES DEPARTMENT		
	Fresenius Vial Le Grand Chemin, 38590 Brézins	
	CUSTOMER SERVICE	Tel.: 00 33 (0) 4 76 67 10 81 or 00 33 (0) 4 76 67 10 54 or 00 33 (0) 4 76 67 11 08 Fax: 00 33 (0) 4 76 67 11 34
	SALES MANAGEMENT	Tel.: 00 33 (0) 4 76 67 10 81 Fax: 00 33 (0) 4 76 67 11 34
TRAINING DEPARTMENT		
	Fresenius Vial Le Grand Chemin, 38590 Brézins	Tel.: 00 33 (0) 4 76 67 10 76 Tel.: 00 33 (0) 4 76 67 11 40 Fax: 00 33 (0) 4 76 67 11 22
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	Spare parts departement	Tel.: 00 33 (0) 4 76 67 10 34
BELGIUM	**FRESENIUS VIAL** NV/SA Vial Médical Division Molenberglei 7 2627 Schelle BELGIUM	Tel.: 00 32 (3) 8 80 73 07 Fax: 00 32 (3) 8 80 50 07
GERMANY	**FRESENIUS MCM** AM-Neuen Berg 63749 ALZENAU GERMANY	Tel.: 49/60 23 97 22-0 Fax: 49/60 23 43 06

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